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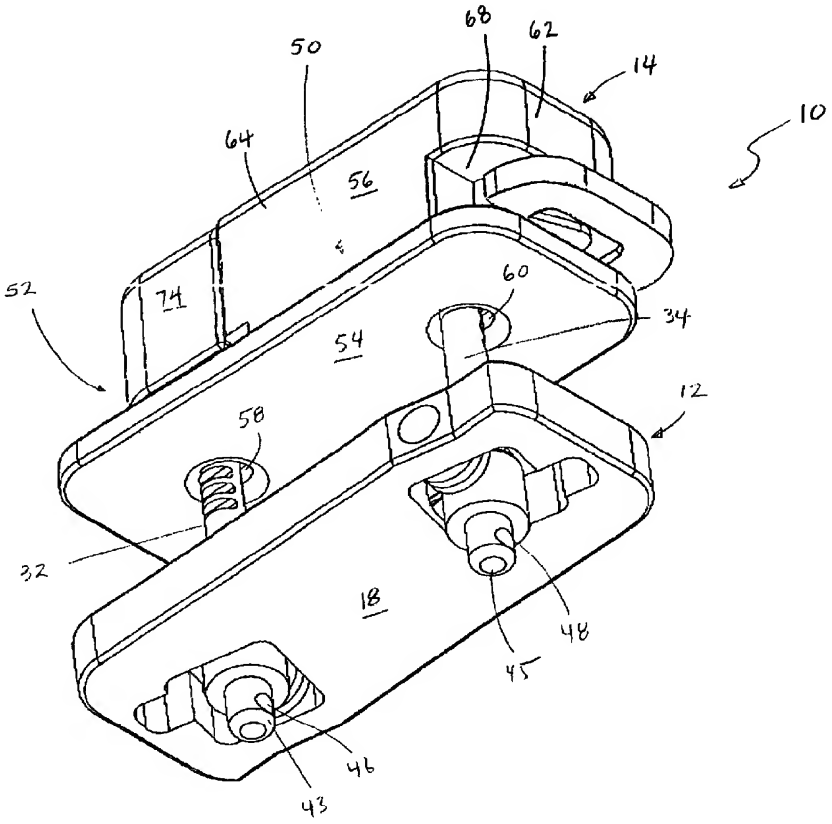
(54) Title: SURGICAL FASTENER PARTICULARLY FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (GERD)



(57) Abstract: A surgical instrument includes an end effector having a clevis and first and second jaws mutually rotatable between open and closed positions. The jaws are proximally directed and laterally displaced relative to a longitudinal axis of a control shaft of the instrument. The jaws hold first and second parts of a fastener, respectively. The first part includes a base having upstanding tissue piercing posts, and the second part includes another base defining apertures for receiving the posts, as well as a portion movable relative to the second base. When the upstanding posts are inserted into the apertures, the movable portion can be moved into a second configuration to lock the parts of the fastener together. The instrument is adapted to move the second part into the second configuration. A method for using the apparatus and fastener are also provided.

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SURGICAL FASTENER PARTICULARLY FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Technical Field

The invention relates to surgical fasteners, endoscopic surgical instruments, and procedures. More particularly, the invention relates to surgical fasteners, endoscopic instruments, and procedures for the transoral plication and fastening together of portions of the stomach for the treatment of GERD.

Background Art

Gastroesophageal reflux disease (GERD) or persistent heartburn is caused by an improper relaxation of the lower esophageal sphincter (LES) that allows the frequent regurgitation of acidic stomach contents into the esophagus. If left untreated, chronic reflux may cause esophageal stricture, bleeding ulcers, perforation, and scarring. Continued reflux may lead to Barrett's esophagus, which involves changes in the cells that make up the esophagus and may lead to cancer.

The current mode of treatment is primarily pharmacological starting with antacids and progressing to proton pump inhibitors (PPIs). The progression of the disease is noted by the development of a hiatal hernia caused by the stomach being forced into the thoracic cavity. The pharmacological treatment ends with double and triple dosing of PPIs. At the point that the patient is not responding to the PPIs, surgical intervention is often recommended.

The current standard for surgery is the Nissen fundoplication. The fundoplication procedure involves wrapping the fundus of the stomach around the lower end of the esophagus and fastening it in place to make the lower esophageal sphincter

(LES) less compliable. Traditionally, this procedure is accomplished via open surgery with the use of sutures to secure the plicated fundus of the stomach around the esophagus without penetrating (incising) the stomach. However, with the advent of laparoscopic surgery came the development of a corresponding laparoscopic Nissen procedure.

In an effort to further reduce the invasiveness of treatment for GERD, endoscopic techniques are being explored. Techniques that are currently under trials include the implantation of bulking agents, cautery techniques to produce scarring, and suturing or otherwise fastening internal tissue.

For example, U.S. Patent Number 5,403,326 to Harrison et al. discloses a method of performing endoscopic fundoplication using surgical staples or two-part surgical fasteners. The procedure disclosed by Harrison et al. involves performing two percutaneous endoscopic gastrotomies (incisions through the skin into the stomach) and the installation of two ports through which a stapler, an endoscope, and an esophageal manipulator (invagination device) are inserted. Under view of the endoscope, the esophageal manipulator is used to pull the interior of the esophagus into the stomach. When the esophagus is in position, with the fundus of the stomach plicated, the stapler is moved into position around the lower end of the esophagus and the plicated fundus is stapled to the esophagus. The process is repeated at different axial and rotary positions until the desired fundoplication is achieved. While, the procedure disclosed by Harrison et al. is a vast improvement over open surgery, it is still relatively invasive requiring two incisions through the stomach.

U.S. Patent Number 5,571,116 to Bolanos et al. discloses a non-invasive treatment of gastroesophageal reflux disease which utilizes a remotely operable invagination device and a remotely operable surgical stapler, both of which are inserted transorally

through the esophagus. According to the methods disclosed by Bolanos et al., the invagination device is inserted first and is used to clamp the gastroesophageal junction. The device is then moved distally, pulling the clamped gastroesophageal junction into the stomach, thereby invaginating the junction and involuting the surrounding fundic wall. The stapler is then inserted transorally and delivered to the invaginated junction where it is used to staple the fundic wall.

Bolanos et al. disclose several different invagination devices and several different staplers. Generally, each of the staplers disclosed by Bolanos et al. has an elongate body and a spring biased anvil which is rotatable approximately 15 degrees away from the body in order to locate the invaginated gastroesophageal junction between the body and the anvil. The body contains a staple cartridge holding a plurality of staples, and a staple firing knife. Each of the invagination devices disclosed by Bolanos et al. has a jaw member which is rotatable by at least 45 degrees and in some cases more than 90 degrees to an open position for grasping the gastroesophageal junction. One of the chief disadvantages of the methods and apparatus disclosed by Bolanos et al. is that the stapler and the invagination device are separately inserted but must both be present in the esophagus at the same time. With some of the embodiments disclosed, the presence of both instruments is significantly challenged by the size of the esophagus. Moreover, the esophagus cannot form a seal about both the instruments and, thus, it is difficult to insufflate the stomach to facilitate the procedure. In addition, the actuating mechanism of the device disclosed by Bolanos et al. is awkward. In particular, the stapler anvil is biased to the open position, and it is not clear whether or not the stapler anvil can be locked in a closed position without continuously holding down a lever. In addition, it appears that the staple firing trigger can be inadvertently operated before the anvil is

in the closed position. This would result in inadvertent ejection of staples into the stomach or the esophagus of the patient.

U.S. Patent Number 6,086,600 to Kortenbach discloses an endoscopic surgical instrument adapted to perform fundoplication, between the stomach wall and the esophagus. The instrument includes a flexible tube, a grasping and fastening end effector coupled to the distal end of the tube, and a manual actuator coupled to the proximal end of the tube. The manual actuator is coupled to the end effector by a plurality of flexible cables which extend through the tube. The tube contains a lumen for receiving a manipulable endoscope and the end effector includes a passage for the distal end of the endoscope. The end effector has a store for a plurality of male fastener parts, a store for a plurality of female fastener parts, a rotatable grasper, a rotatable fastener head for aligning a female fastener part and a male fastener part with tissues therebetween, and a firing member for pressing a male fastener part through tissues grasped by the grasper and into a female fastener part. According to a stated preferred embodiment, the overall diameters of the flexible tube and the end effector (when rotated to the open position) do not exceed approximately 20 mm so that the instrument may be delivered transorally to the fundus of the stomach.

While transoral fundoplication devices and methods hold promise, it is still difficult to deliver and manipulate the necessary apparatus transorally. One reason for the difficulty is that the overall diameter, or more accurately the cross sectional area, of the equipment is too large. Moreover, even if the Kortenbach device could be reduced to 20 mm in diameter (314 mm^2 cross sectional area), it would still be difficult to manipulate. Those skilled in the art will appreciate that larger instruments are less pliable and the plication and fastening procedure requires that the instruments be retroflexed nearly 180

degrees. Moreover, it will be appreciated that large instruments obscure the endoscopic view of the surgical site.

Recently, PCT WO 00/78227 (NDO Surgical Inc.) has disclosed a device sized to receive an endoscope and which is purportedly capable of plicating and damaging portions of the stomach wall to effect serosa-to-serosa contact which results in stomach wall tissue adhesion. As a result, compliance of the tissue about the esophagus would be reduced and a flap (i.e., valve) would be formed about the LES. For this purpose, the plication and adhesion should preferably be created at the horseshoe-shaped tissue in the stomach surrounding the LES. The distance from the Z line (esophageal/stomach borderline) to the horseshoe-shaped target tissue is approximately 1 to 3 cm into the stomach and plication at this location permits the greatest stress to be placed on the tissue about the LES. In order to approach plication at this location the device has a particularly complicated and unwieldy multi-component end effector adapted to grab tissue, plicate the tissue, and fasten the tissue together. That is, while the above referenced device appears to offer a solution, it may not be practical to implement mechanically or operate during the procedure. Further, the above referenced device, while respectfully having a relatively smaller diameter than other prior art (approximately 18 mm in diameter and 254 mm^2 in cross-sectional area) maintains that cross-sectional area over its entire length. In addition to limited flexibility, the size of the device renders it difficult to traverse the tracheopharangeal passage. Moreover, while it is desirable to plicate the stomach wall in a direction parallel to the esophagus in order to satisfactorily reduce compliance of the tissue, it is noted that the end effector of the above referenced device is unable to approach the target tissue from the desired direction.

It is also preferable that any fastener used for the apposition of tissue in the stomach cavity be removable in the

event of tissue ischemia, vagus nerve irritation, or continued reflux, and be relatively non-injurious to the patient should the fastener inadvertently become loose from the device or dislodged from the tissue. In addition, current fasteners are difficult to locate within the stomach via an endoscope if it becomes necessary to find the fastener for removal.

Disclosure of the Invention

It is therefore an object of the invention to provide methods and apparatus for transoral plication and fastening of tissue of the stomach wall.

It is another object of the invention to provide an apparatus for transoral plication and fastening of tissue which is adapted to form a plication at a location substantially adjacent the lower esophageal sphincter (LES).

It is also an object of the invention to provide an apparatus for transoral plication and fastening of tissue which is adapted to approach the stomach tissue in a direction substantially parallel to the esophagus.

It is an additional object of the invention to provide an apparatus that has a relatively small cross-sectional area and is adapted for transoral plication and fastening of tissue.

It is a further object of the invention to provide an endoscopic apparatus for transoral plication and fastening of tissue which can be detached from the endoscope while the endoscope is located within the stomach.

It is a further object of the invention to provide methods and apparatus for transoral plication and fastening of tissue which damages tissue such that adhesion occurs during healing.

It is still another object of the invention to provide a tissue fastener which will not cause ischemia and which, if necessary, is relatively easily endoscopically removable from the stomach.

It is still a further object of the invention to provide a fastener which, if inadvertently released into the stomach, will not cause harm to the gastrointestinal tract.

It is yet another object of the invention to provide a fastener which can easily be identified in the stomach with an endoscope.

In accord with these objects which will be discussed in detail below, a two-part fastener, and an instrument and system for application of the fastener to the stomach wall in a manner which effectively treats gastroesophageal reflux disease (GERD) are provided.

The fastener includes male and female parts which can be adjustably coupled together to define various spaces therebetween such that depending on the amount of tissue between the components a desired amount of force can be applied to the tissue therebetween by the fastener, i.e., such that the tissue does not necrose. The male part includes a plurality of tissue-piercing posts which are spring-biased to collapse into a base of the male part to prevent injury to the patient should the male part inadvertently become separated from its respective jaw prior to coupling with the female part or separated from the female part after coupling therewith. In addition, the female part is provided with a cover which shields the piercing tips of the posts after the male and female parts are coupled together. The fastener when in a fastened configuration may be unfastened by moving portions of the cover relative to each other. This can be performed, e.g., using a snare device to lasso the device and moves portions of the female part relative to each other.

The instrument includes a relatively short distal end effector which may be coupled over a portion of the endoscope, a proximal actuation handle, and a relatively small diameter control shaft extending between the handle and the end effector. As only the control shaft extends from the handle of the

instrument to the end effector, during use, the cross-sectional area of the system within the esophagus at all locations other than the distal end of the instrument, is substantially small (the sum of the areas of the endoscope and the control shaft); i.e., less than half that of other proposed systems. In addition, at the distal end of the instrument, the system cross-sectional area is also smaller than that of prior art systems.

More particularly, the distal end effector may be provided with a sleeve that can be slidably positioned over the end of the endoscope and likewise slidably removed therefrom. The sleeve is preferably proximally and distally tapered to ease insertion into and removal from the esophagus. The distal end effector also includes a clevis about which a pair of rotatable jaws are coupled. The jaws are laterally displaced relative to the control shaft. The jaws are each adapted to each hold one part of the two-part fastener. When the jaws are in a closed position with the parts of the fastener located therebetween, the jaws extend substantially parallel to the longitudinal axis of the control shaft. That is, the jaw assembly is fixed in a retroflexed or "looking back" arrangement, directed 180° from the distal end of the control shaft. In addition, the jaws and fastener parts together define posts adapted to grab the stomach tissue, pierce and damage the serosa of the stomach tissue, and plicate the stomach tissue when the jaws are moved from an open position to a closed position.

The instrument includes a first control element that moves the jaws between open and closed positions, and a second control element that couples the fastener parts together and releases the fastener parts from the jaws.

One embodiment of using the system includes sliding the sleeve of the instrument over the distal end of the endoscope and moving the sleeve to a central location on the scope. The endoscope is next inserted through the tracheoesophageal passage

and into the stomach. The distal end of the instrument, with the jaws in a closed low profile configuration, is then slid over the endoscope, through the tracheoesophageal passage, into the stomach, and off the distal end of the endoscope. The endoscope may be retroflexed during a portion of the insertion of the distal end of the instrument such that the instrument insertion is performed under view of the endoscope.

The jaws of the instrument are then opened by actuation of the handle, and the handle and/or control shaft are pulled back to cause the open jaws to forcibly contact the stomach tissue surrounding the lower esophageal sphincter; i.e., the target tissue 1 cm to 3 cm into the stomach. As the jaws contact the tissue, a post on the female jaw and the posts of the male part of the fastener pierce the mucosa, deep muscle and/or serosa of the tissue. An endoscopic grasping instrument extending through the endoscope may be used in conjunction with the end effector to aid in pulling the target tissue between the jaws. The handle is then actuated to cause the jaws to move into a closed position, pulling into apposition two portions of the tissue to form a plication. The posts of the male part of the fastener extend through both layers of tissue at the ends of the plication and enter corresponding openings in the female part as the jaws are closed and the fastener is clamped, but not locked, about the tissue. If desired, the jaws can then be opened to apply a different clamping pressure to the tissue or entirely relocate the fastener. Once the fastener is in a desired location and with a desired pressure on the tissue, the handle is actuated to lock the fastener and release the fastener from the jaws. The instrument may then be recoupled to the endoscope, and the endoscope and the instrument may be withdrawn from the patient.

Other instruments and methodologies which provide other couplings between the instrument and the endoscope, and which do

not require any coupling of the instrument to the endoscope are also provided.

Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.

Brief Description of Drawings

Fig. 1 is a bottom perspective view of a two-part tissue fastener with male and female parts thereof shown mated but in an unlocked configuration;

Fig. 2 is a perspective view of a male part of the two-part fastener of Fig. 1, shown with posts of the male part in an upright configuration;

Fig. 3 is a perspective view of a male part of the two-part fastener, similar to Fig. 2, shown with posts of the male part in a collapsed configuration;

Fig. 4 is a top perspective view of the two-part tissue fastener in the same configuration as Fig. 1;

Fig. 5 is a bottom perspective view of the two-part tissue fastener in the same configuration as Fig. 1, shown with the latch body removed from the female part of the fastener to facilitate viewing the interior structure of the female part of the fastener;

Fig. 6 is a bottom perspective view of a two-part tissue fastener with male and female parts thereof shown mated and in a locked configuration;

Fig. 7 is a bottom perspective view of the two-part tissue fastener in the same configuration as Fig. 6, shown with the latch body removed from the female part of the fastener to facilitate viewing the configuration of the interior structure of the female part of the fastener;

Fig. 8 is a perspective view of an alternate post of a male part of the fastener and an alternate sliding assembly of a female part of the fastener;

Fig. 9 is a broken side view of an endoluminal tissue plication and fastener applicator instrument according to the invention, shown with a fastener in the end effector;

Fig. 10 is a side end perspective view of the distal end of the instrument of Fig. 9, shown with a fastener in the end effector;

Fig. 11 is a top perspective view of the distal end of the instrument of Fig. 9, shown with a fastener in the end effector, but without the female jaw torsion spring;

Fig. 12 is a perspective view of the distal end of the instrument, with control shaft removed for clarity, and shown with the jaws in an open configuration and without the fastener;

Fig. 13 is a view similar to Fig. 12, shown with the fastener.

Fig. 14 is a perspective view of the distal end of the instrument, with control shaft removed for clarity, and shown with the jaws in a closed configuration and without the fastener;

Fig. 15 is a side elevation view of the distal end of the instrument, with control shaft removed for clarity, and shown with the jaws in a closed configuration and without the fastener;

Fig. 16 is a perspective view of the distal end of the instrument, with control shaft removed for clarity, and shown with the jaws in an open configuration and without the fastener;

Fig. 17 is a perspective view of the distal end of the instrument, with control shaft removed for clarity, and shown with the jaws in a closed configuration and without the fastener;

Fig. 18 is a perspective view of the distal end of the instrument, with the control shaft and the mounting sleeve removed for clarity, and shown with the jaws in an open configuration with a fastener;

Fig. 19 is a plan view of the distal end of the instrument, with the control shaft and the mounting sleeve removed for clarity, and shown with the jaws in a closed configuration with a fastener;

Fig. 20 is a perspective view of the distal end of the instrument, with the control shaft and the mounting sleeve removed for clarity, and shown with the jaws in a closed configuration without a fastener;

Fig. 21 is a partial view of the proximal actuation handle of the instrument of the invention;

Fig. 22 illustrates the instrument of the invention coupled to an endoscope during insertion of the two into the stomach;

Fig. 23A is an end view schematic illustration of a cross-sectional area across line 23A-23A in Fig. 9 across a portion of the distal end effector of the instrument;

Fig. 23B is an end view schematic illustration of a cross-sectional area across line 23B-23B in Fig. 9 across a portion of the distal end effector of the instrument;

Fig. 24 is a schematic illustration of the cross-sectional area of the endoscope and the control shaft;

Fig. 25 is a schematic illustration of the cross-sectional area of a prior art device;

Fig. 26 illustrates the instrument separated from the endoscope and shown with the jaws in an open position;

Fig. 27 is a view similar to Fig. 26, and additionally shows a grasping instrument advanced through the endoscope and engaging the target tissue at which a plication is desired to be made;

Fig. 28 illustrates the jaws of the instrument plicating the target tissue and the fastener in a locked configuration;

Fig. 29 illustrates the jaws of the instrument in an open position and the fastener holding the plicated tissue together;

Fig. 30 illustrates an alternate embodiment of the procedure in which the end effector is operated while coupled to an endoscope;

Fig. 31 is a side elevation of a second embodiment of the distal end effector adapted to be coupled in the distal opening of a working channel of an endoscope;

Fig. 32 is a perspective view of the second embodiment of the distal end effector shown in Fig. 31;

Fig. 33 is a side perspective view of a third embodiment of the distal end effector adapted to be advanced over a guidewire;

Fig. 34 rear perspective view of the third embodiment of the distal end effector shown in Fig. 33;

Figs. 35 through 45 illustrate a second embodiment of the procedure in which the end effector is advanced over a guidewire into the stomach and operated under view of an endoscope;

Fig. 46 is an end view schematic illustration of a cross-sectional area across line 46-46 in Fig. 33; and

Fig. 47 is an end view schematic illustration of a cross-sectional area across line 46-46 in Fig. 33.

Best Mode for Carrying Out the Invention

Turning now to Fig. 1, a two-part fastener 10 according to the invention is shown. The fastener 10 includes male and female parts 12, 14. Referring to Figs. 1 and 2, the male part 12 includes a base 18 defining two openings 20, 22 therethrough and, in one side, two elongate channels 24, 26 and two spring shelves 28, 30. Two tissue-piercing posts 32, 34 are rotatably coupled to the base 18 in alignment with the channels 24, 26. Each posts includes an enlarged portion 33, 35 having a diametric bore (not shown). Axles 36, 38 extend across openings 20, 22, through the bores, and are press-fit into the base 18 such that the posts 32, 34 are rotatable thereabout. The posts 32, 34 have a length of preferably at least 2 mm such that they are adapted to penetrate

the serosa of the stomach tissue, and a diameter of preferably less than 1.5 mm inch so that the holes made thereby in the stomach tissue are not prone to leakage. Furthermore, while the posts 32, 34 are adapted to pierce tissue, they are also slightly rounded at the tips so as to preferably only displace tissue rather than cut tissue. Torsion springs 40, 42 are coupled to the posts 32, 34 and are stopped against the base 18 at the shelves 28, 30. Referring to Figs. 1 through 3, the torsion springs 40, 42 operate to bias the posts 32, 34 toward a collapsed configuration in which the posts lie within the channels 24, 26. The channels 24, 26 are oriented at an angle within the base 18 to accommodate posts 32, 34 of a maximized length for the size of the base 18. An upper portion of each post 32, 34 is provided with a plurality of slots (notches or grooves) 44 along a medial side thereof, and a lower end 43, 45 of each post is provided with a diametric bore 46, 48.

Referring to Figs. 1, 4 and 5, the female part 14 includes a latch body 50 and a sliding assembly 52 which is slidably movable relative to the latch body. Referring particularly to Fig. 1, the latch body 50 includes a base portion 54 and a cover (or shield) portion 56 which are manufactured as a single unit or a fixed assembly of separate elements. The base portion 54 includes two holes 58, 60, each sized to receive a post 32, 34 therethrough and preferably having chamfered openings. The cover portion 56 is preferably U-shaped, having an end portion 62 and two sides 64, 66 that extend around a portion of the periphery of the base portion 54. The end portion 62 of the cover portion 56 defines a lower recess 68 and opening 69 at the recess 68.

The sliding assembly 52 includes a latch slide 70, a latch lock 72, and a slide cover (or shield) 74. Referring particularly to Fig. 5, the latch slide 70 defines two elongate slots 82, 84, a lower recess 86, a head portion 76 having a relatively larger width than the remainder of the slide, and

cutouts 78 between the head portion 76 and the remainder of the slide. The latch lock 72 resides in recess 86 and the recess is shaped to stably hold a central portion 88 of the lock 72 and to provide space for lateral displacement of elongate portions of the lock 72. More particularly, the lock 72 includes a generally Z-shaped central portion 88, and two arms 90, 92 extending from a central extension 91 of the central portion 88. Arm 90 includes a central laterally extending stop 94 and, at its terminus, a beveled catch 96. Arm 92 includes a central beveled catch 98, and at its terminus, a laterally extending stop 100. Each arm 90, 92 is biased in the direction of the extension of its stop 94, 100, with the bevel of its catch 96, 98 directed toward a respective slot 82, 84. The latch slide 70, with latch lock 72 positioned therein, is slidably inserted through the opening 69 of the cover portion 56 of the latch body 50, and the slide cover 74 is then fixed onto the latch slide 70 with pins 104 that are press fit into respective coupling holes 106, 108 (Figs. 4 and 5). It is appreciated that the latch lock 72 is retained in the recess 86 by the base portion 54 of the latch body 50. The slide cover 74 defines a central space 110. In addition, referring to Figs. 5, the latch slide 70 and slide cover 74 define a setback 112 at which the female part 14 can be engaged with an applicator instrument 200 (Fig. 9), as described further below.

By way of example only, preferred dimensions for one exemplar fastener sized for being passed through the esophagus and coupling portions of the stomach tissue together are as follows. The male part 12 has a length of 15 mm, a width of 6.25 mm, and a height of 2 mm (excluding the posts). The female part 14 has a length of 15 mm, a width of 6.25 mm, and a height of 4 mm. The coupled fastener 10 has overall dimensions of a length of 15 mm, a width of 6.25 mm, and a height of 6 mm plus the thickness of the tissue between the male and female parts.

The parts 12, 14 are preferably constructed of titanium or titanium alloy, and then anodized according to processes known in the art of metallurgy to impart to the parts a color distinct from the natural tissue of the stomach cavity. Preferred colors include purple, blue and black.

As discussed in more detail below, when the male and female parts 12, 14 of the fastener 10 are brought into apposition on opposite sides of tissue located therebetween by the below described instrument 200 (Fig. 9) (with the posts 32, 34 of the male part 12 held upright against the bias of the torsion springs 40, 42, as detailed below), the posts 32, 34 of the male part 12 can pierce through tissue and extend into the holes 58, 60 of the base portion 54 of the female part 14 (Fig. 1). The chamfered openings of the holes 58, 60 facilitate this mating by guiding the posts into the holes 58, 60 even if the parts 12, 14 are slightly misaligned. The male and female parts 12, 14 of the fastener 10 are then clamped about the tissue. The slide cover 74 and cover portion 56 shield the sharp portions of posts 32, 34, respectively, which extend through the base portion 54 of the female part 14.

Referring now to Figs. 6 and 7, once the fastener 10 is clamped about tissue with a desired clamping force (or desired pressure), the sliding assembly 52 is longitudinally slidable relative to the latch body 50 until the head 76 of the latch slide 70 abuts the cover portion 56 within the recess 68 and until the catches 96, 98 on the latch lock 72 ride against their bias into respective slots 44 of the posts 32, 34, thereby locking the male and female parts 12, 14 together. The plurality of slots 44 and the substantial length of the posts 32, 34 permits the base 18 of the male part 12 and base portion 54 of the female part 12, 14 to be coupled at several distances relative to each other. In addition, the base 18 and base portion 54 may even be skewed relative to each other to further

accommodate various configurations of tissue therebetween, with the catches 96, 98 entering, for example, a third notch of post 32 and a fourth notch of post 34. As a result of this adjustability, a desired amount of force can be applied to tissue between the parts 12, 14, whether or not the tissue therebetween is of uniform thickness, and with such force preferably limited to prevent tissue necrosis.

Furthermore, it is noted that when the sliding assembly 52 is moved relative to the latch body 50, the catches 96, 98 will automatically find an appropriate slot 44, as the latch lock 72 is spring-loaded and compliant. That is, should a catch 96, 98 of the latch lock 72 initially contact a post 32, 34 at a non-slotted location, the compliance of the latch lock 72 will cause the catch 32, 34 to snap into an adjacent slot 44 when subject to small additional movement.

It is also noted that the movement of the sliding assembly 52 relative to the latch body 50 causes the slide cover 74 to be spaced apart from the latch body cover 56. This opens a space 108 between the slide cover 74 and the latch body cover 56.

Even after the male and female parts 12, 14 have been locked together, they may be unlocked from each other. Moving the sliding assembly 52 in an opposite direction relative to latch body 54, such that the slide cover 74 and cover portion 56 are moved relatively closer together, operates to unlock the male and female parts 12, 14 such that they may then be separated from each other. That is, this mechanism facilitates decoupling of a fastener and thereby permits atraumatic retrieval of an implanted fastener. One manner of effecting the decoupling can be performed with a standard endoscopic snare device. A loop of the snare device is provided over and about the slide cover 74 and cover portion 56 and the two parts are pulled toward each other by decreasing the size of the snare loop. A portion of the snare loop may be positioned through recess 68 to prevent the loop from

slipping off the fastener 10. Moreover, it is noted that the unnatural color of the fastener 10 relative to the tissue of the stomach cavity facilitates endoscopically locating an implanted fastener for such retrieval.

As discussed above, the posts 32, 34 are spring-biased to collapse into a base of the male component when not retained against the bias. This operates to prevent injury to the patient should the male part 12 inadvertently become separated from the applicator instrument 200 or from the female part 14 after coupling therewith. Given the size of the parts and the protection of sharps from exposure to the body, the parts may be safely passed through the gastrointestinal system.

It is recognized that various other configurations for locking the latch lock 72 of the female part 14 relative to the posts 32, 34 of the male part 12 can be used. For example, referring to Fig. 8, the posts 32a may be provided with circumferential grooves 44a. And the latch lock 72a may have another configuration which effectively provides a catch which can be locked within the grooves 44a. In Fig. 8, the latch lock 72a includes, for post 32a, two resilient, spaced-apart, spring-biased arms 92a, 93a each with a catch 98a, 99a adapted to engage within a groove on the post 32a and, for the second post (not shown), two resilient, spaced-apart, spring-biased arms 90a, 91a each with a catch 96a, 97a adapted to engage within a groove on the post.

As further discussed below and clearly shown in the figures relating thereto, the parts 12, 14 of the fastener 10 are delivered through the esophagus in a lengthwise orientation.

Turning now to Fig. 9, an endoluminal tissue plication and fastener applicator instrument 200 is shown. The instrument 200 generally includes a distal end effector 202, a proximal actuation handle 204, and a tubular control shaft 206 housing first and second control elements 208, 210 (wire, cables, coils,

ribbons, etc.) extending between the handle 204 and the end effector 202.

The control shaft 206 is preferably a stainless-steel flat wire wound coil covered in a lubricious sheath, and is substantially smaller in diameter than a conventional endoscope. The flat wire limits elongation of the control shaft when the control shaft is under tension due one or the other of the control elements 208, 210 being under compression. Alternatively, a rounded wire coil can be used which permits the control shaft to bend into a tighter radius than the flat wire wound coil. In addition, the control shaft 206 has a relatively small diameter relative to the distal end effector 202, preferably not exceeding 5 mm and more preferably approximately 4 mm.

The distal end effector 202 is adapted to plicate tissue and apply the two-part fastener 10 to opposed sections of the plicated tissue, and according to several embodiments is optionally adapted to be coupled to an endoscope, as described in detail below. The actuation handle 204 operates the control elements 208, 210 to effect clamping and opening of the jaw assembly 218 and locking and release of the fastener 10, as also described in detail below.

Referring now to Figs. 10 through 12, the distal end effector 202 includes a jaw assembly 218 having a clevis 224, first and second arms 220, 222 mutually rotatable about the clevis 224, a housing 290, and a sleeve (continuous or slit cuff) 320 integral with the housing 290 and adapted to be slidably positioned about (or, if slit, snapped over) an end of an endoscope.

The first arm 220 of the jaw assembly 218 includes a male jaw 226 (adapted to receive the male part 12 of the fastener 10), and an opposite tang 230 having a coupling hole 232 adapted to receive a wire-like element. The second arm 222 includes a

female jaw 228 (adapted to receive the female part 14 of the fastener 10), and an opposite tang 234 having a coupling hole 236.

More particularly, the inside of the male jaw 226 includes a rectangular recess 240 adapted to receive the back of the male part 12 of the fastener 10, two stepped throughbores 242, 244, and two threaded holes 248, 250. Referring to Figs. 3 and 13, when the male part 12 is loaded into and held within the recess 240 of the male jaw 226, the lower portions 43, 45 as well as portions of the enlarged portions 33, 35 of the posts 32, 34 are received in the stepped throughbores 242, 244. This retains the posts 32, 34 in an upright configuration and consequently prevents their rotation into a collapsed configuration. Referring back Figs. 10 and 12, the outside of the male jaw 226 also includes a recess 246 through which the threaded holes 248, 250 are accessed, and an exit opening 252 in communication with a track 258 (which carries a release element, discussed below) through the first arm 220. The end of the male jaw 226 is also provided with a groove 254, the function of which is described below.

A first release element 259 extends within the track 258 of the first arm 220 from a housing 290 of the clevis 224 and through the exit opening 252. The first release element 259 includes an actuation end 255 which is split to define two U-shaped portions 261, 263 which are respectively inserted into the bores 46, 48 (Fig. 3) of the lower end 43, 45 of the posts 32, 34 of the male part of the fastener. Friction plates 265, 267 are held over the U-shaped portions 261, 263, with screws 271, 273 inserted into the threaded holes 248, 250, to provide frictional resistance from inadvertently dislodging the U-shaped portions from within the bores 46, 48.

Referring to Figs. 11 through 13, the female jaw 228 includes a relatively large generally rectangular opening 260

sized to receive the latch body cover 56 and latch slide cover 74 of the female part 14 of the fastener 10. The jaw 228 also defines a ledge 275 (Fig. 16), and two catches 262, 264 that extend into the opening. The female part 14 is inserted into the jaw 228 in the locked position and then moved into the unlocked position such that the head 76 of the latch slide 70 (Fig. 5) lies over the ledge 275 and the catches 262, 264 extend within the setback 112 (Fig. 5) to lock the part 14 in the jaw 228. A tissue piercing post 256 is provided to the terminus of the female jaw 228. Referring to Figs. 14 and 15, when the female and male jaws 226, 228 are free of the fastener parts 12, 14 and closed together (e.g., after the fastener has been released and during retraction of the instrument), the post 256 resides in the groove 254 of the male jaw 226 to provide a more tapered configuration to aid in removal of the instrument from the patient.

Referring now to Figs. 15 and 16, a torsion spring 266 is coupled to the female jaw 228 and adapted to force the female part 14 of the fastener 10 toward the terminus of the jaw. This operates to help align the male and female parts 12, 14 as the jaws 226, 228 are rotated toward each other through an arc. Moreover, the spring 266 permits movement of the female part 14 within the opening 260 to accommodate misalignment due to the amount of the tissue between the fastener parts. Referring to Figs. 16 and 17, the female jaw 228 also includes an exit opening 268 for a wire track 270 extending along a side of arm 222. A second release element 272 extends within the track 270 from the housing 290 through the exit opening 268, as described further below.

Referring now to Fig. 18, the clevis 224 also includes a mount 280 at which the control shaft 206 (Fig. 9) is attached to the distal end effector 202 of the instrument 200. The mount 280 includes a bracket 282 that is coupled to the clevis 224 at pivot

284. The clevis 224 also defines a housing 290 for a mechanical assembly 292 which operates to transmit an input force on the control elements 208, 210 to the end effector 202 to effect movement of the jaw arms 220, 222 and locking and release of the fastener 10 therefrom.

More particularly, the mechanical assembly 292 preferably includes a first bell crank 294 rotatably coupled about a pivot 296 that is preferably integrally formed with the housing. A distal end 298 of control element 208 is coupled to the first bell crank 294 at an input side of the bell crank, and a V-shaped wire 300 is attached to the bell crank at an output side of the bell crank. The V-shaped wire 300extends to and is coupled within the coupling holes 232, 236 (Fig. 12) of the tangs 230, 234 of both of the two jaw arms 220, 222. Alternatively, two separate wires can be used to extend from the output side of the bell crank to the two tangs. Referring to Figs. 18 and 19, when control element 208 is moved distally relative to the control shaft, the first bell crank 294 is rotated, pulling the V-shaped wire 300 away from the jaws and thereby rotating the jaws 226, 228 into a closed position. Still referring to Figs. 18 and 19, it is also noted that when the jaws 226, 228 are forced into a completely closed position, additional force on control element 208 causes rotation of the mount 280 about the pivot 284 to cause the jaws to move closer to the control shaft 206. This reduces the profile of the end effector to aid in removal of the instrument from the stomach and esophagus after a fastener 10 has been released from the instrument 200. When control element 208 is moved proximally relative to the control shaft 206, the first bell crank 294 is rotated to cause the V-shaped wire 300 to forcibly rotate the jaws 226, 228 into an open position. In addition, referring back to Fig. 18, when the jaws 226, 228 are in a fully opened position, additional force on control element 208 causes rotation of the mount 280 about the pivot 284 which

pushes the jaw assembly 218 away from the control shaft 206. This provides additional space between the jaw assembly 218 and the control shaft 206 to facilitate grabbing tissue between the jaws 226, 228.

Referring still to Figs. 18 and 19, the mechanical assembly 292 also includes a second bell crank 302 that is rotatably coupled about a pivot 304 which is also preferably integrally formed with housing 290. A distal end 306 of control element 210 is attached to one side of the second bell crank 302. Another side of the second bell crank 302 defines a push bar 310. The ends of release elements 259, 272 (Fig. 17) terminating within the housing 290 are preferably bent or otherwise formed at an angle such as to define contact portions 312, 314 (Figs. 18 and 19) which, when the jaw arms 220, 222 are in a closed position (Fig. 19), are oriented substantially perpendicular to the orientation of the push bar 310.

Referring now to Figs. 19 and 20, when the jaws are in a closed position and control element 210 is pushed distally relative to the control shaft 206 to apply a pushing force to the second bell crank 302, the push bar 310 is forced against the contact portions 312, 314 and moves the release elements 259, 272 (Fig. 16) into the respective jaws 226, 228. This effects both locking together the male and female parts 12, 14 of the fastener 10 and release of fastener 10 from the jaws 226, 228, as follows. First, when the end of release element 272 is pushed against the sliding assembly 52, the sliding assembly is forced to move relative to the latch body 50. This locks the catches 96, 98 of the latch lock 72 relative to the posts 32, 34, and thereby locks the male and female parts 12, 14 of the fastener together. Second, movement of the sliding assembly spaces moves the latch slide cover 74 to free the head 76 of the latch slide from the ledge 275 and free the catches 262, 264 of the female jaw 228 from the setback 112 (aligning space 108 (Fig. 6) with the

catches 262, 264), to thereby release the female part 14 from the female jaw 228. Third, the U-shaped ends 261, 263 (Fig. 10) of the bifurcated release element 255 are moved out of the bores 46, 48 of the posts 32, 34 to release the male part 12 from the male jaw 226. It is noted that the force on release element 255 is sufficient to overcome the friction created by plates 265, 267.

It is noted that the push bar 310 is decoupled from the release elements 259, 272 as the contact portions 312, 314 of the release elements will be differently located relative to the push bar 310 based upon whether large or small amounts of tissue are located between the closed jaws 226, 228 and to what degree the jaws are closed. This decoupled adjustable mechanism operates to effect the appropriate amount of movement to the release elements regardless of the exact closed jaw configuration.

Alternatively, rather than use a bell crank system in which control element 208 is placed under tension to close the jaws and control element 210 is placed under compression to operate the lock the fastener parts and release the fastener from the jaws, another system may be used to couple the control elements 208, 210 to the jaws 226, 228 and release elements 259, 272, respectively. For example, each of the control elements may include an end provided with a U-shape in which the end of the control element defines a return extending non-coaxial but parallel to the remainder of the control element. For example, the U-shaped end of the control element 208 can be coupled to the jaws such that when control element is placed under compression the return portion of the U-shape pulls the jaws closed. Similarly, the U-shaped end of the control element 210 can be configured to act on release elements 259, 272 such that control element is placed under tension to the U-shaped portion pushed on the release elements 259, 272. Other mechanisms may likewise be used.

Referring back to Figs. 10 and 11, the sleeve 320 of the distal end effector 218 preferably has an opening 321 with a diameter of approximately 9 mm, corresponding to the diameter of a relatively small endoscope. The exterior dimensions of the sleeve 320 are minimized to provide as low a profile as possible to facilitate passage of the distal end effector 218 through the tracheoesophageal passage of a patient. The sleeve 320 may also be provided with a slant nose or other tapered or otherwise streamlined shape that further facilitates introduction and withdrawal of the distal end effector 202 through the tracheoesophageal passage. In addition, the sleeve 320 is preferably constructed of a preferably soft, low friction, lubricious material such as polytetrafluoroethylene (PTFE), nylon, or silicone to aid in movement over the endoscope and prevent injury to the human body. The sleeve 320 is coupled over the housing 290 to enclose the mechanical assembly 292 (Fig. 18). To facilitate the coupling of the sleeve 320 to the end effector 202, it is preferable that the sleeve 320 be provided with two holes 322, 324 and that pivots 296 and 304 (Fig. 18) for the first and second bell cranks 294, 302 be provided with an internal thread (Fig. 18). Screws 326, 328 are inserted in holes 322, 324 and thread into the pivots 296, 304 to lock the sleeve over the housing 290.

Referring now to Figs. 9 and 21, the proximal actuation handle 204, which according to one embodiment is a pistol-grip style handle, includes a stationary handle 340, and a lever 342 rotatable relative thereto. The stationary handle 340 is integral with a housing 344 which defines a longitudinal slot 346. A proximal end 356 of the control shaft 206 extends into the housing 344 and is coupled to an upper portion of the lever 342. The first control element 208, which is coupled at its distal end 298 to the jaw arms 220, 222 via the first bell crank 294, includes a proximal end 358 that extends out of the proximal

end 356 of the control shaft 206 and is fixed at a second mount 360 within the housing 344. The second control element 210, which operates to lock and release the fastener 10 via the second bell crank 302, includes a proximal end 362 that is coupled to a cross bar 364 movable within the longitudinal slot 346. The cross bar 364 includes a handle portion 365 (Fig. 9) located external the housing 344. The lever 342 is biased into an open position with a first spring 350 that is coupled between a lever mount 352 on the lever and a first mount 354 within the housing 344. The lever 342 is also provided with a locking system 366 that operates to lock the position of the lever relative to the handle 340. The locking system 366 includes a plurality of teeth 368 on the lever, a pawl 370 mounted on a pivot 372 and biased with a second spring 374 toward the teeth 368, and a cam 376 that can be manually rotated with an external knob 378 (Fig. 9) to contact the pawl 370 and effect disengagement of the pawl from the teeth 368.

In operation, when the handle lever 342 is rotated toward to the stationary handle 340, the control shaft 206 is moved distally relative to the first control element 208 to effect closing the jaws 226, 228. With the jaws in a closed position, the cross bar 364 can be moved distally relative to the stationary handle 340 in order to operate the second bell crank 302 (via control element 210) to cause lock and release of the fastener 10. After a fastener 10 is released, the cam 376 can be operated to release the handle locking system 366 and permit the handle lever 342 to rotate relative to the stationary handle 340, thereby allowing the jaws to reopen.

While a pistol-grip embodiment of the handle 340 has been shown for operation of the instrument 200, as such a handle includes significant mechanical advantage, it may be preferred to use an inline-type handle or other handle configured to also provide the desired mechanical advantage.

The instrument 200 is highly torqueable with great ability to direct the end effector via manipulation of the handle in gross. That is, the instrument 200 has a torsionally rigid flexible shaft particularly for its length of at least approximately 150 cm, and more likely 190 cm length. This torqueability permits the end effector assembly 212 to be rotated through 180° (for any approach toward the target tissue) via rotation of the handle preferably by no more than approximately 180°. This is facilitated, in part, by control element 208 being rotational fixed to the handle 340. Control element 208 is relatively large in diameter, and is most preferably an approximately 0.035 inch stainless steel wire. A wire of similar construct having a diameter preferably between approximately 0.020 inch and approximately 0.062 inch should also be suitable.

According to one embodiment of the method of the invention, the instrument 200 may be operated as follows with respect to the treatment of GERD. Turning to Fig. 22, the sleeve 320 of the distal end effector 202 is slidably coupled over the distal end of an endoscope 400 and the end effector is slid proximally over the endoscope. The distal end of the endoscope 400 is then inserted into the tracheopharangeal passage and moved through the esophagus and into the stomach, with the end effector 202 of the instrument 200 mounted preferably approximately 20 cm back from the distal end of the endoscope 400. The handle 204 and/or control shaft 206 are then manipulated in gross to slide the distal end effector 202 over the distal end of the inserted endoscope 400 and into the stomach, with the endoscope 400 functioning as a guidewire for the sleeve 320. The endoscope 400 may optionally be retroflexed to look back toward to the LES 402 of the esophagus and visualize the advancement of the end effector 202.

Referring to Fig. 23A, it is particularly noted that during insertion of the end effector over the endoscope and into the

patient (and later withdrawal of the end effector from the patient), the maximum cross-sectional area of the system extending within the esophagus occurs with the combined area of the sleeve 320 and the portion of the clevis 224 that extends outside the footprint of the sleeve; i.e., approximately 188 mm^2, smaller than any of the existing or proposed devices in the prior art. The second largest cross-sectional area of the system within the esophagus is at the location of the jaws 226, 228 with the jaws loaded with a fastener 10. Referring to Fig. 23B, this area includes the footprint of the jaw assembly 218 loaded with a fastener as well as the control shaft 206 and the endoscope 400, and is approximately 178 mm^2. The portions of the system having the cross-sectional areas of Figs. 23A and 23B are located within the esophagus only during insertion and removal of the end effector into the patient. Referring to Fig. 24, at all other times and along all other portions of the present system proximal the distal end effector, the cross-sectional area of the system in the esophagus is substantially smaller, limited to the combined cross-sectional areas of the endoscope 400 (approximately 63.6 mm^2 for a 9 mm scope) and the control shaft 206 (approximately 12.6 mm^2 for a 4 mm control shaft); i.e., a total cross-sectional area of approximately 76.2 mm^2 or less.

In contrast, prior art Fig. 25 shows the relative size of a cross-sectional area corresponding to a prior art device 900 having an 18 mm diameter (254 mm^2), such as the NDO device described above in the State of the Art section. This relatively larger area obstructs the esophagus throughout the procedure.

If the endoscope is retroflexed during insertion of the distal end effector 202, the passage of the distal end effector into the stomach is performed under view of the endoscope 400. Once the distal end effector is located in the stomach, the endoscope is preferably straightened if it was retroflexed, and the end effector is moved distally off the endoscope such that

the endoscope 400 and instrument 200 are completely separated. Referring to Fig. 26, the endoscope 400 is then again retroflexed and the instrument handle 204 is operated to open the jaws 226, 228 of the end effector 202, as described above.

Referring to Fig. 27, a tissue grasping instrument 406, e.g., a forceps, helical needle, or tagging device, is preferably then inserted through a working channel 408 of the endoscope 400 and directed at target tissue 410 one to three centimeters into the stomach adjacent the LES where the center of a plication is to be located. The grasping instrument 406 engages the tissue 410 and pulls the tissue back between the jaws 226, 228 of the end effector 202 of the instrument 200. In addition, the handle 204 and/or control shaft 206 of the instrument 200 are pulled back in gross (i.e., in the direction of withdrawing the instrument) such that the jaws approach the tissue 410 in a direction substantially parallel to the esophagus. This is a highly desirable angle of approach that has been previously unattainable with endoscopic GERD treatment instruments. That is, any device that retroflexes must extend through an arc. It is not possible for a retroflexed device to be both parallel to an entry path and also displaced a couple of centimeters away from the entry path.

The proximal actuation handle 204 is then operated to cause the jaws 226, 228 to close. As a central point of the tissue 410 is held in a fixed location between the jaws by the grasping instrument 406 during movement of the jaws, a tissue plication 412 if formed by the jaws and the male and female parts 12, 14 of the fastener 10 are brought together with the plication 412 clamped therebetween. When the jaws 226, 228 are closed about the tissue plication 412, the posts 32, 34 of the male part 12 of the fastener 10 preferably pierce the tissue down to the serosa, and the piercing post 256 of the female jaw 228 preferably pierces through the deep muscle of the tissue and sufficiently to

damage the tissue to cause serosa to serosa contact. Experimental procedures have shown that this contact results in tissue adhesion after healing, such that the tissue is permanently reconfigured; i.e., even if the fastener 10 is later removed. In this manner, a zone of reduced compliance is created about the LES.

The location and size of the plication as well as the relative positions of the fastener parts are observed via the scope. Moreover, more or less clamping pressure can be applied to the plicated tissue by control of the proximal actuation handle 204.

Referring to Fig. 29, if the plication 412 appears satisfactory, the proximal actuation handle 204 is then operated, as described above, to lock the male and female parts 12, 14 of the fastener 10 and release the coupled fastener from the jaws 226, 228. If the plication or fastener position is not satisfactory, prior to locking and release, the jaws can be opened, reoriented if necessary, and another plication can be formed.

After the fastener is applied, the jaws are then closed, the endoscope is straightened, and the end effector is preferably re-docked over the distal end of the endoscope. The instrument and endoscope are preferably together withdrawn through the esophagus and out of the patient. Alternatively, the endoscope may be withdrawn first, followed by the withdrawal of the instrument preferably under visualization.

As discussed above, if at any time the fastener or either of the parts thereof become loose during the implantation procedure or any time after the procedure, the sharps on the fastener elements are adapted to assume a safe configuration or are permanently covered. As such, the fastener or its parts may be safely passed through the gastrointestinal system of the patient.

While it is preferable to decouple the instrument from the endoscope during the procedure, it is appreciated that the instrument may be operated while coupled to the endoscope. That is, referring to Fig. 30, the target tissue is approached by opening the jaws 226, 228 and simply retracting the instrument 200 along the endoscope 400 until the tissue about the LES is contacted. The jaws 226, 228 are then closed and the fastener 10 applied, as described above. In order to utilize this procedure, the sleeve 320 of the instrument should be offset relative to the jaws 226, 228 so that the jaws can clear the endoscope when opening and closing.

Turning now to Figs. 31 and 32, a first alternative embodiment of a distal end effector 502 of the instrument 200 according to the invention is shown. The end effector 502 is adapted to couple within the distal end of a working channel of an endoscope, rather than be coupled about the endoscope with a sleeve. To that end, the housing 590 of the end effector 502 is provided with a proximally directed peg 620 preferably located above, but in line with the control shaft 206, and sized to be received within the distal end of a working channel of an endoscope. In addition, the housing 590 also includes a concave surface 622 permitting the housing 590 and endoscope to be adjacent in a minimized profile.

In use, the end effector is docked with the distal end of the endoscope using the peg 620, and the control shaft 206 is held taught relative to the endoscope to maintain the coupling. The cross-sectional area for the system at the end effector (end effector and endoscope coupled together) is approximately 150 mm^2. It is noted that the cross-sectional area of the system is smaller than the area defined by a system utilizing a sleeve, as the endoscope is close fitting with the end effector and the sleeve dimensions are eliminated. The endoscope, with end effector 502 attached at its distal end, is then inserted into

the patient's stomach. The proximal handle 204 and/or control shaft 206 is then manipulated in gross to disengage the end effector. Thereafter, the procedure continues, preferably as discussed above, until plication and fastener application is achieved. Then, prior to removal of the instrument and endoscope, the end effector 502 is preferably re-docked with the endoscope, and the instrument and endoscope are withdrawn from the patient. Alternatively, the endoscope and instrument are separately removed.

While the instrument has been shown adapted to be coupled to an endoscope, it is recognized that the instrument may be modified for use in a manner in which it is always decoupled from an endoscope. Referring now to Figs. 33 and 34, a second alternate embodiment of the distal end effector 702 of the instrument 200 is shown. The housing 790 of the end effector 702 is provided with a tapered nose piece 820 defining a longitudinal passage 822 sized to receive a guidewire 824. The guidewire may have a diameter less than one millimeter. The nose piece 820 is preferably formed from a highly flexible material such as silicone.

According to a preferred method of use, referring to Fig. 35, an endoscope 400 is preferably first inserted through the tracheopharangeal passage 414 and into the stomach 416 in accord with a well-known procedure. Next, referring to Fig. 36, a guidewire 924 is advanced through the endoscope into the stomach. Referring to Fig. 37, the endoscope 400 is then preferably withdrawn from over the guidewire 824. Referring to Fig. 38, the end effector 702 is then blindly advanced over the guidewire 924 and introduced into the stomach 416. The tapered nose piece 820 and relatively small head-on cross-sectional area of the system facilitate the introduction. Referring to Fig. 39, after the end effector 702 is located in the stomach 716, the guidewire 824 is preferably withdrawn from the stomach. Referring now to Figs. 40

and 41, the endoscope is then reintroduced alongside the control shaft of the instrument, advanced into the stomach and retroflexed to view the end effector 702. The jaws 726, 728 of the end effector 702 are also opened and brought adjacent the tissue which is to be plicated. Referring to Fig. 42, a tissue grabbing device 920 is deployed through a working channel of the endoscope 400 and operated to engage tissue 910 at a location at which the fold of a plication is desired. The tissue grabbing device preferably includes piercers which extend through the mucosa and the muscularis (deep muscle) to thereby hold these layers together and prevent delamination. Turning to Fig. 43, the jaws of the end effector 702 are closed, forming a plication 812 about the engaged tissue 910, the plication 912 being substantially parallel to the esophagus. The plication extends from the location held by the device 920 to the end of the jaws of the instrument. Referring to Fig. 44, the fastener 10 is deployed and the jaws of the end effector 702 are opened. Referring to Fig. 45, the jaws of the end effector 702 are closed, and the end effector 702 is withdrawn through the esophagus 414 under visualization of the endoscope 400. That is, the closed jaws of the end effector 702 are preferably positioned directly distal of the endoscope 400 to minimize the cross-sectional area of the endoscope/instrument system as well as to permit constant visualization of the end effector during the retraction of the end effector through the esophagus.

It is noted that this embodiment provides the smallest cross-sectional area for the system in the esophagus, as the area is limited to either (1) the end effector, or (2) the endoscope and control shaft, but never both (1) and (2) at the same time. Referring to Fig. 46, for (1), the end effector cross-sectional area across the clevis 790 distal of the jaw assembly is approximately 75 mm^2. Also for (1), the end effector cross-sectional area proximal of the clevis and across the jaw assembly

718 is (with the jaw assembly in a closed position) is approximately 115 mm^2 (calculated as the approximately 102 mm^2 cross-sectional area of the jaw assembly 718 plus the 12.6 mm^2 cross-sectional area of a 4 mm control shaft). For (2), the combined cross-sectional area of the endoscope and control shaft is 76.2 mm^2, calculated as 63.6 mm^2 for a 9 mm endoscope and 12.6 mm^2 for a 4 mm control shaft.

There have been described and illustrated herein several embodiments of fasteners, instruments, systems, and methods for the endoluminal treatment of gastroesophageal reflux disease (GERD). While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. For example, while particular preferred dimensions have been provided for both elements of the instrument and fastener, as well as cross-sectional areas of the system, it is appreciated that the system and its elements may have different relative sizes. For example, the cross-sectional areas can be decreased further if a pediatric endoscope (4 to 6 mm) is used. Also, while a "looking back" instrument has been disclosed particularly for fastener application designed to treat GERD, it is appreciated that a "forward looking" straight instrument with similar jaw assembly can be used to apply the fastener for treatments of other conditions, e.g., obesity, ulceration, stomach cancer, implantation of pH measurement or monitoring devices, feeding tubes, etc. Moreover, a straight device can be smaller in diameter and be operated through a working channel of an endoscope. It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as so claimed.

Claims

1. A surgical fastener, comprising:
a) a first part including a first base provided with at least one stiff upstanding tissue piercing post; and
b) a second part including a second base defining an aperture for receiving each of said at least one stiff upstanding tissue piercing post, and a movable portion, said movable portion movable relative to said second base between first and second configurations,
wherein when said movable portion is in said first configuration and said at least one stiff upstanding post is inserted into a respective aperture, movement of said movable portion into said second configuration locks said first part relative to said second part.

2. A surgical fastener according to claim 1, wherein:
said movable portion and second base are movable from said second configuration into said first configuration to unlock said first part relative to said second part.

3. A surgical fastener according to claim 1, wherein:
said at least one post is adapted to assume a position in which said at least one posts extends substantially perpendicular to said first base.

4. A surgical fastener according to claim 1, wherein:
said movable portion is slidable relative to said second base.

5. A surgical fastener according to claim 1, wherein:
in said second configuration, said movable portion engages with said at least one post.

6. A surgical fastener according to claim 5, wherein:

said at least one post includes at least one groove, and said movable portion includes a catch which engages said at least one groove when said movable portion and said second base are in said second configuration.

7. A surgical fastener according to claim 6, wherein:
said catch is spring-biased.

8. A surgical fastener according to claim 1, wherein:
each of said at least one post includes a tip, and said movable portion includes a first cover portion and said second base includes a second cover portion,
wherein when said at least one post is received through respective apertures in said second base, said first and second cover portions shield said tips of said at least one post when said second base and said movable portion are said second configuration.

9. A surgical fastener, comprising:
a) a first part including a base provided with at least one stiff tissue piercing post, each of said at least one stiff post being rotatable relative to said base about a respective axis; and
b) a second part adapted to receive said at least one post and be mechanically locked relative to said first part.

10. A surgical fastener according to claim 9, wherein:
said at least one post is rotatable between a first position in which said post is substantially perpendicular to said base and a second position in which said post is substantially parallel to said base.

11. A surgical fastener according to claim 10, wherein:

wherein said base defines a channel adapted to receive said at least one post when said at least one post is in said second position.

12. A surgical fastener according to claim 11, wherein: said base defines a longitudinal axis and said channel is skewed relative to said longitudinal axis.

13. A surgical fastener according to claim 10, wherein: said first part further comprises a spring biasing said at least one post into said second position.

14. A surgical fastener according to claim 10, wherein: each said at least one post includes a lower portion that extends through said base when said at least one post is in said first position.

15. A surgical fastener, comprising:
a) a first part including a base provided with at least one stiff post having a tissue piercing tip; and
b) a second part including a base having at least one opening adapted to receive said at least one stiff post and a shield portion, said second part adapted to be mechanically locked relative to said first part,
wherein when said first and second parts are locked relative to each other, said at least one stiff post extends through said at least one opening in said base and said shield shields said tissue piercing tip.

16. A surgical fastener, comprising:
a) a first part including a base provided with at least one post having a tissue piercing tip and defining a plurality of longitudinally displaced engagement structures; and

b) a second part including a base having at least one opening adapted to receive said at least one post, and a catch structure adapted to engage one of said engagement structures on each of said at least one post to thereby lock said first and second parts together.

17. A surgical fastener according to claim 16, wherein: said engagement structures are grooves.

18. A surgical fastener according to claim 17, wherein: said grooves are circumferential about respective posts.

19. A surgical fastener according to claim 17, wherein: said grooves are notches in said respective posts.

20. A surgical fastener according to claim 16, wherein: said catch structure is spring-biased.

21. A surgical fastener according to claim 16, wherein: said catch structure is longitudinally movable relative to said base.

22. A surgical fastener according to claim 16, wherein: said first part includes two posts, and said catch structure is adapted to engage engagement structure at different longitudinal displacements along each of said two posts.

23. A surgical fastener, comprising:
a) a first part including a first base provided with at least one tissue piercing post;
b) a second part including a second base having an opening adapted to receive said at least one post; and

c) means for mechanically locking said first and second parts together regardless of whether said first and second bases are parallel or skewed relative to each other.

24. A surgical fastener, comprising:
a) a first part including a first base provided with at least one tissue piercing post;
b) a second part including a second base having an opening adapted to receive said at least one post; and
c) means for mechanically locking said first and second parts together when said first and second bases are in each of several displacements relative to each other.

25. A surgical fastener, comprising:
a) a first part constructed of titanium or titanium alloy;
b) a second part constructed of titanium or titanium alloy, said first and second parts including cooperating structure adapted to mechanically lock said first and second parts together,
wherein said first and second parts are anodized.

26. A surgical fastener according to claim 25, wherein:
said anodized first and second parts are a color uncommon to a human stomach.

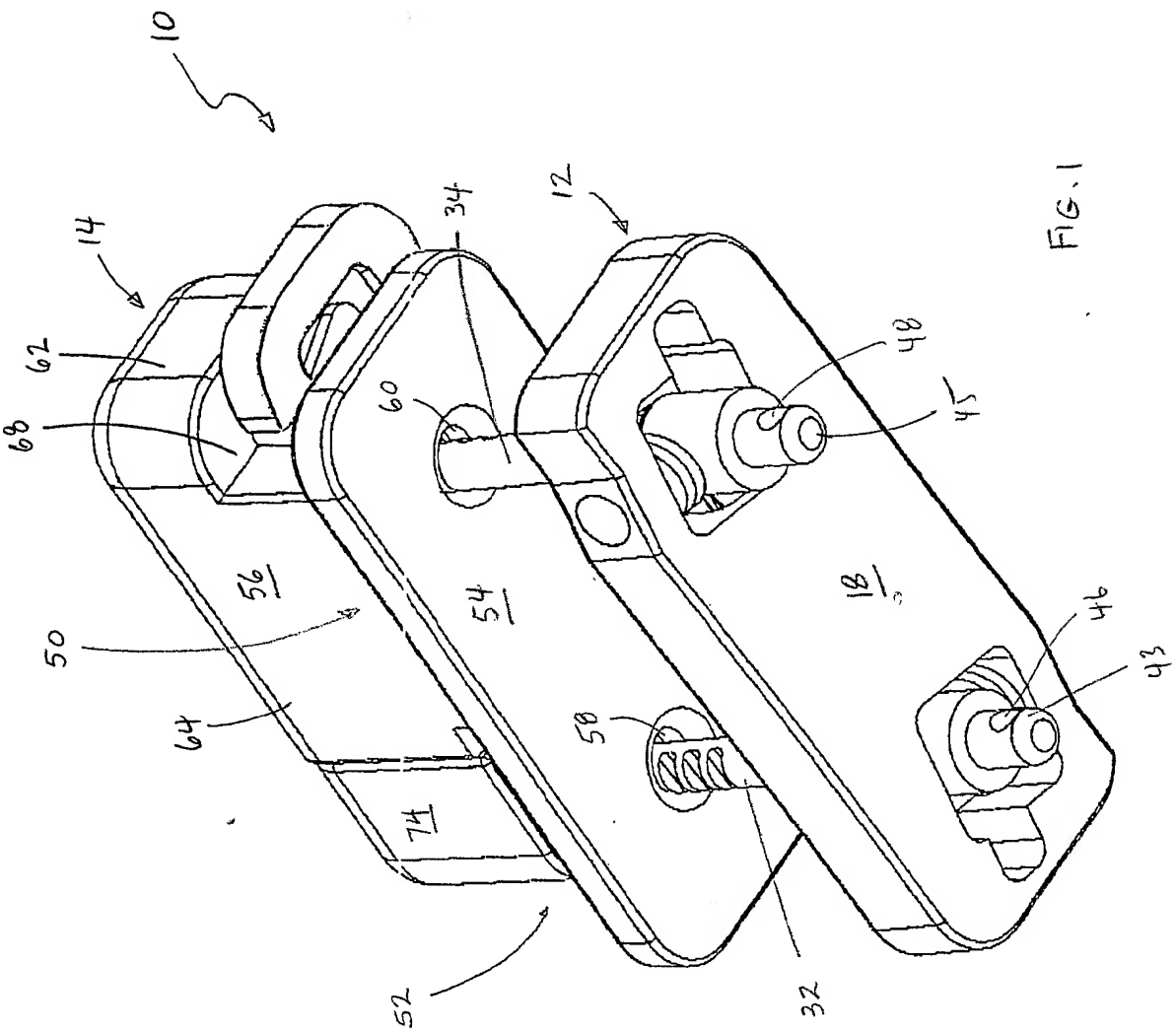


FIG. 1

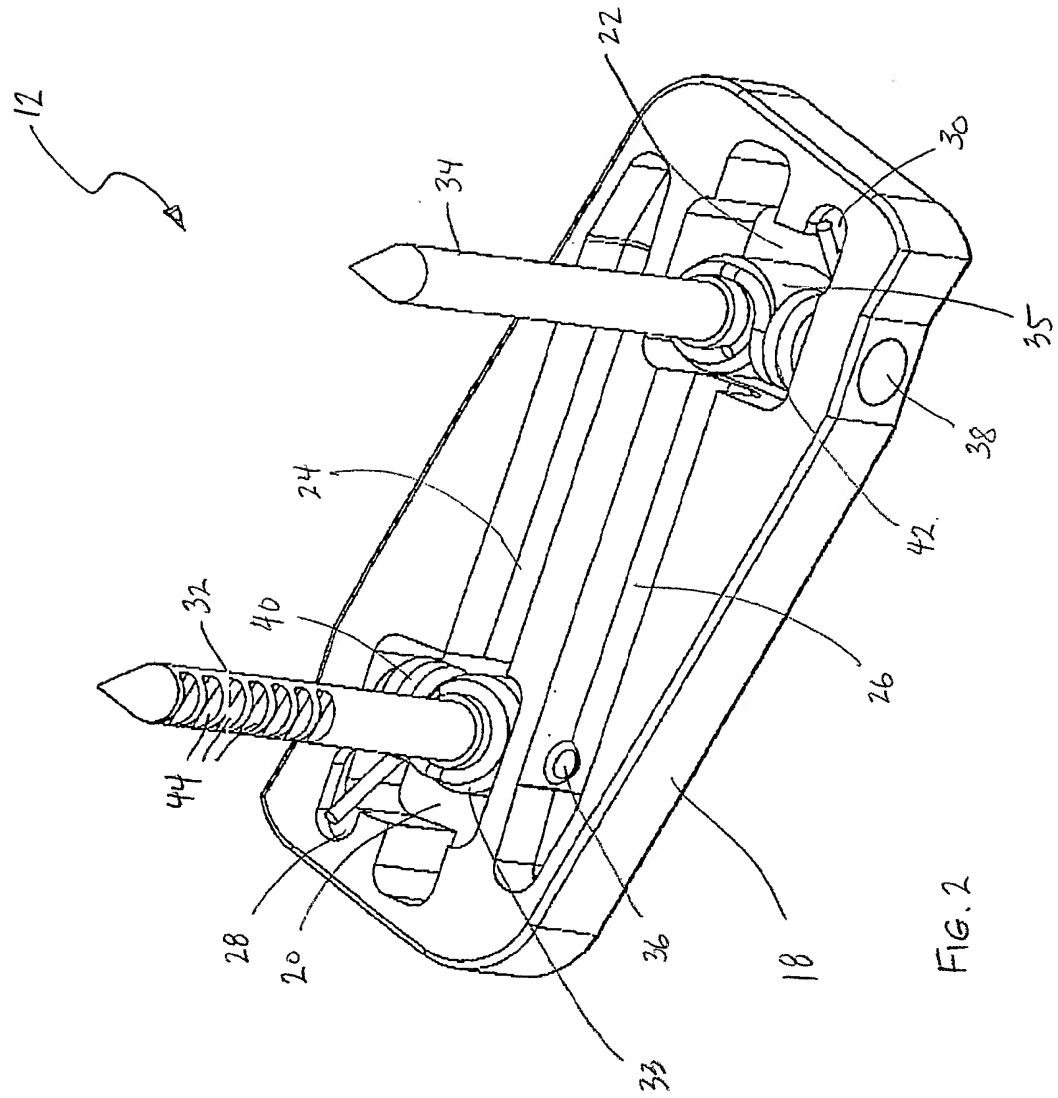


FIG. 2

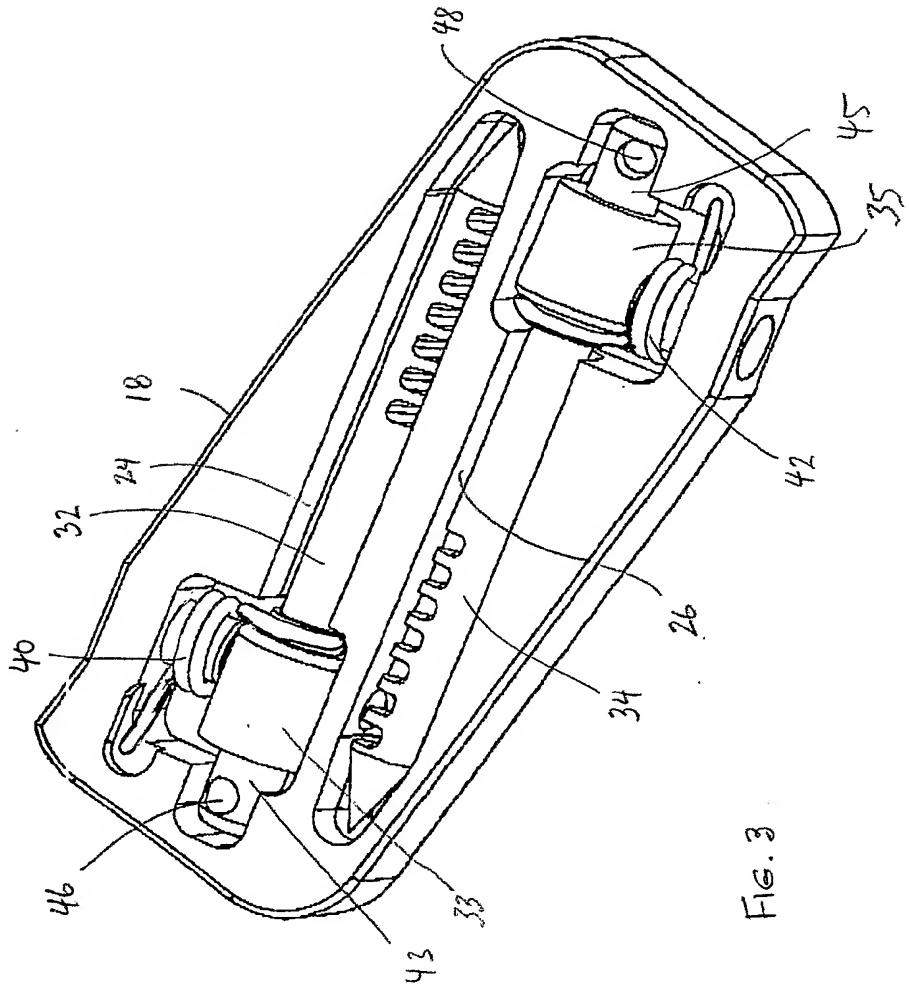
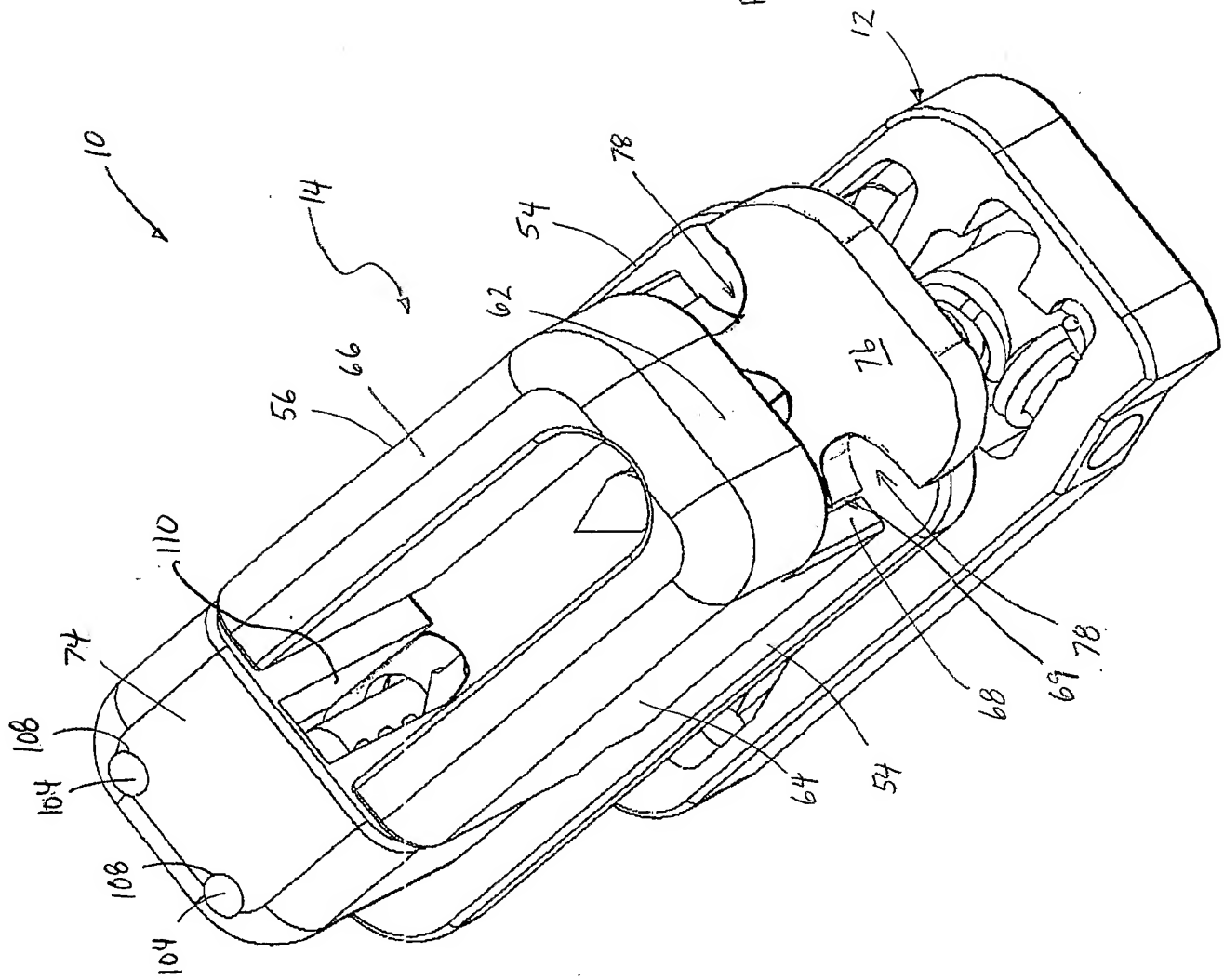


Fig. 3

FIG. 4



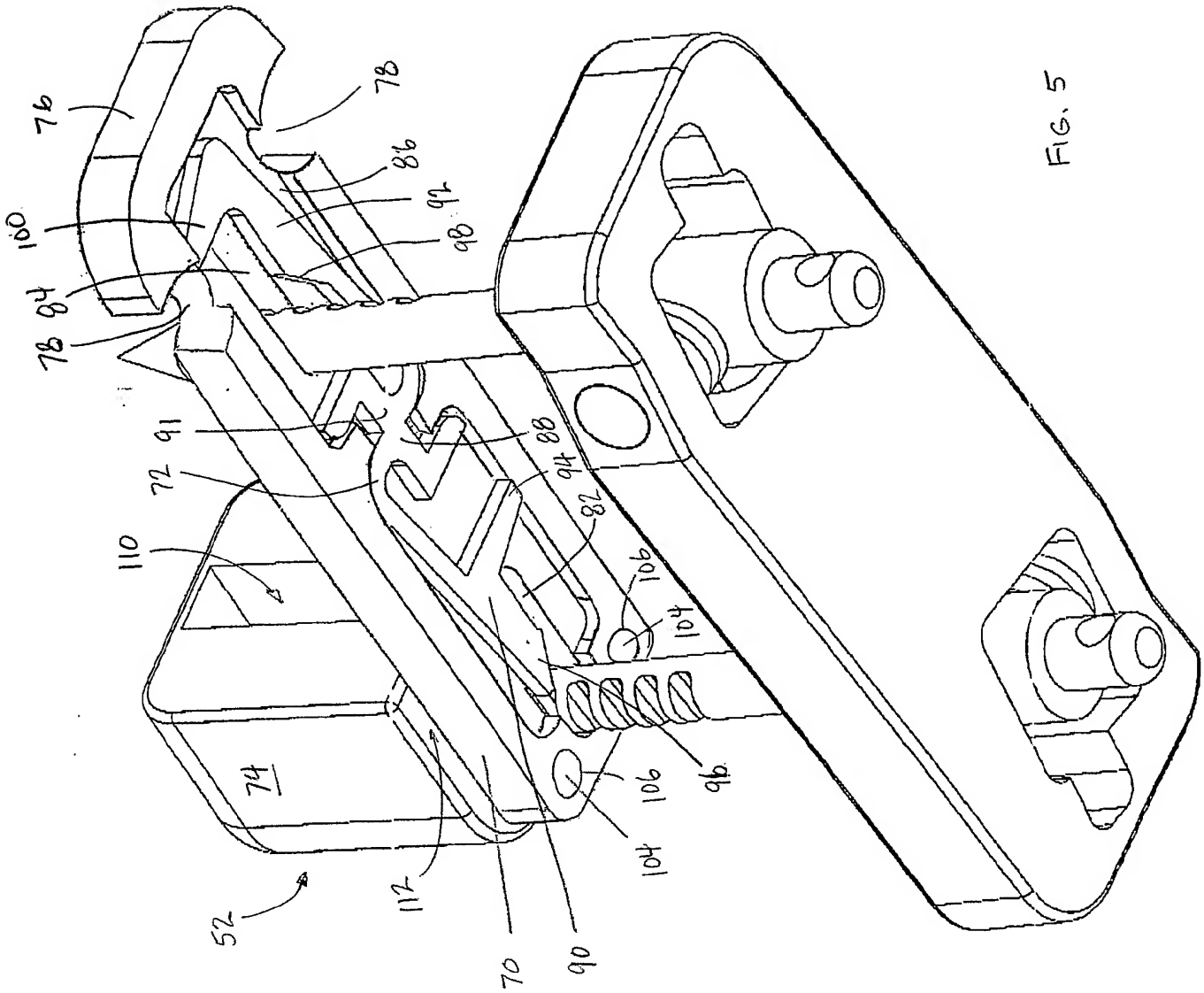

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FIG. 5

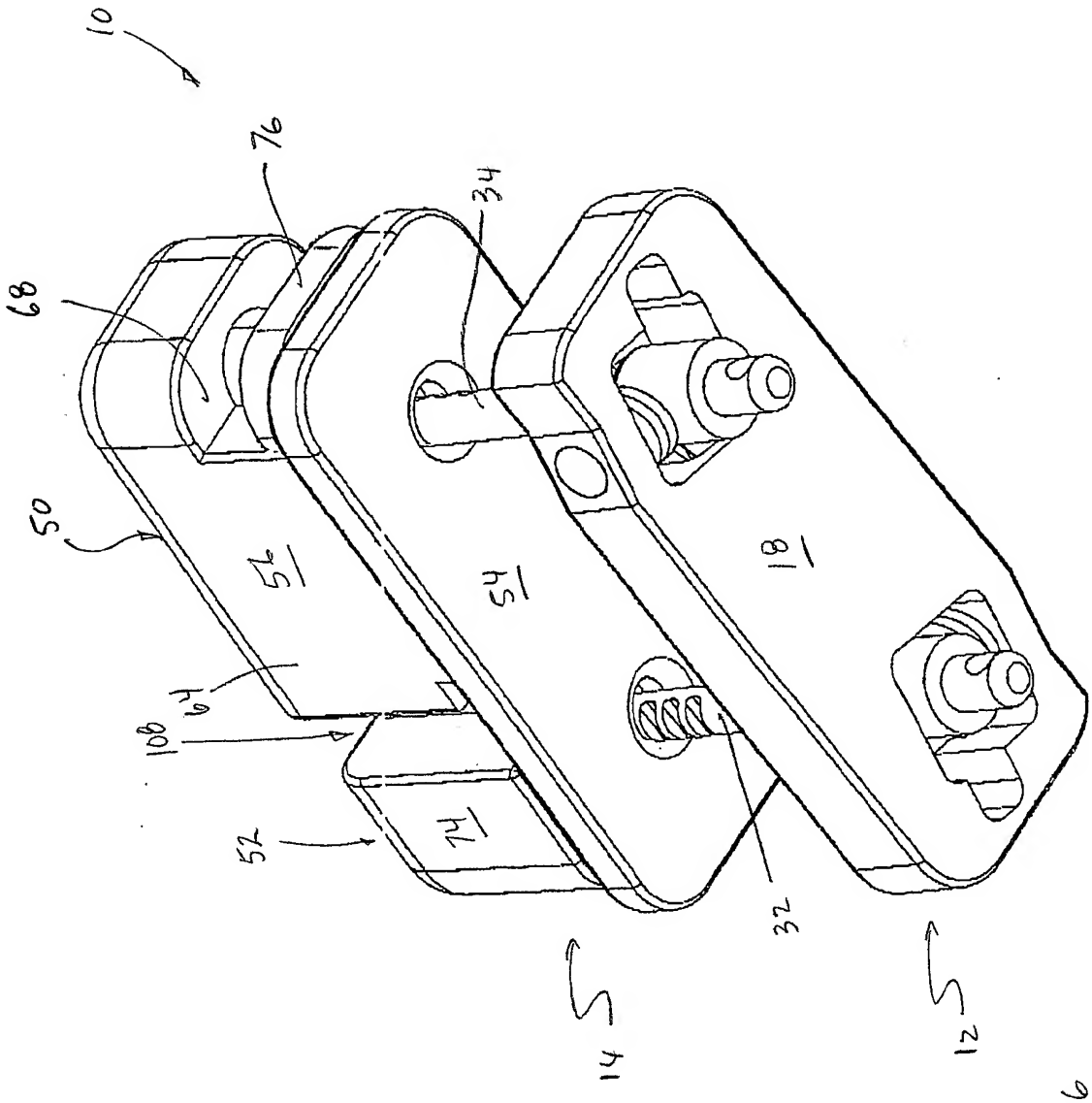

FIG. 6

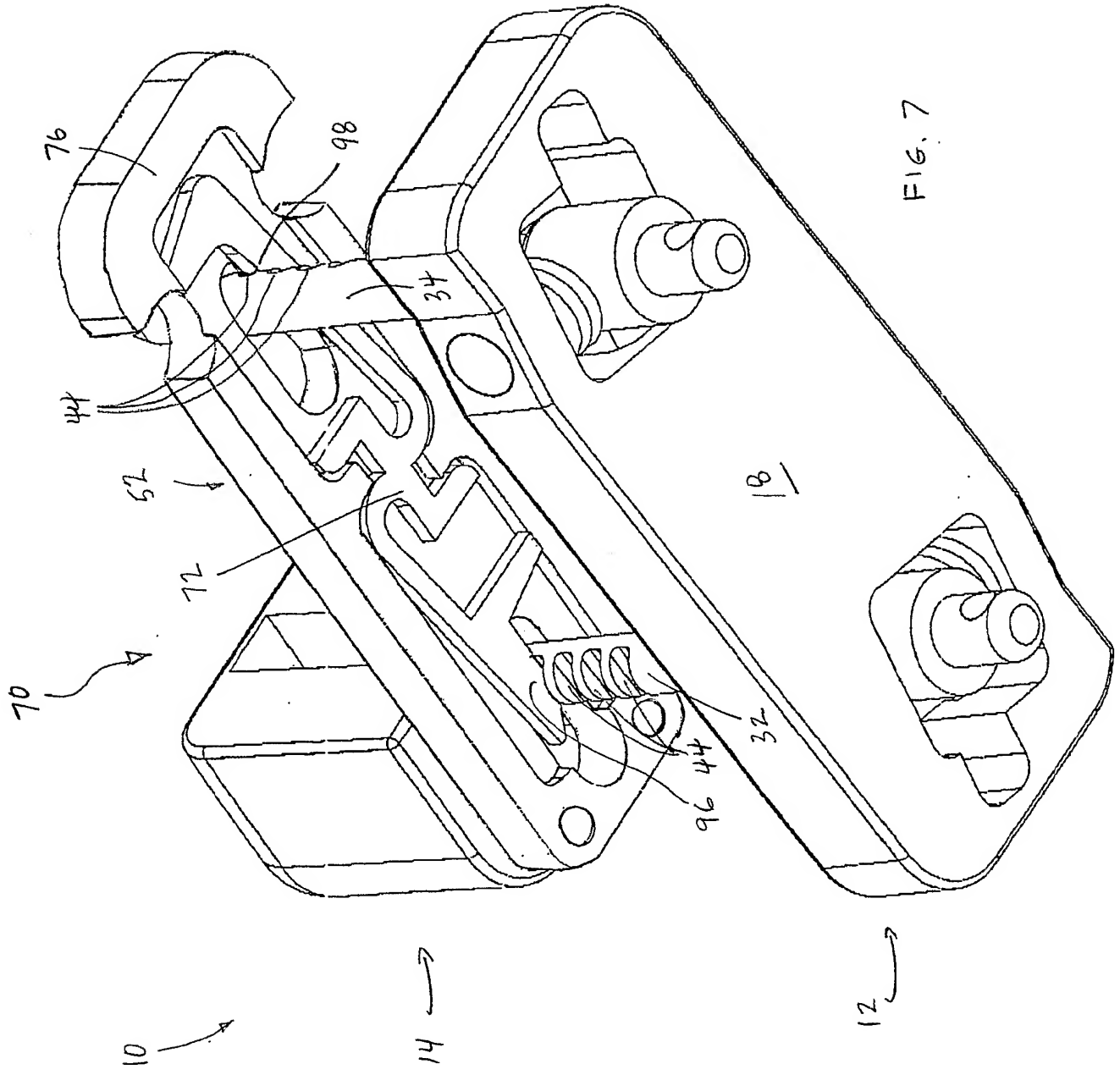

FIG. 7

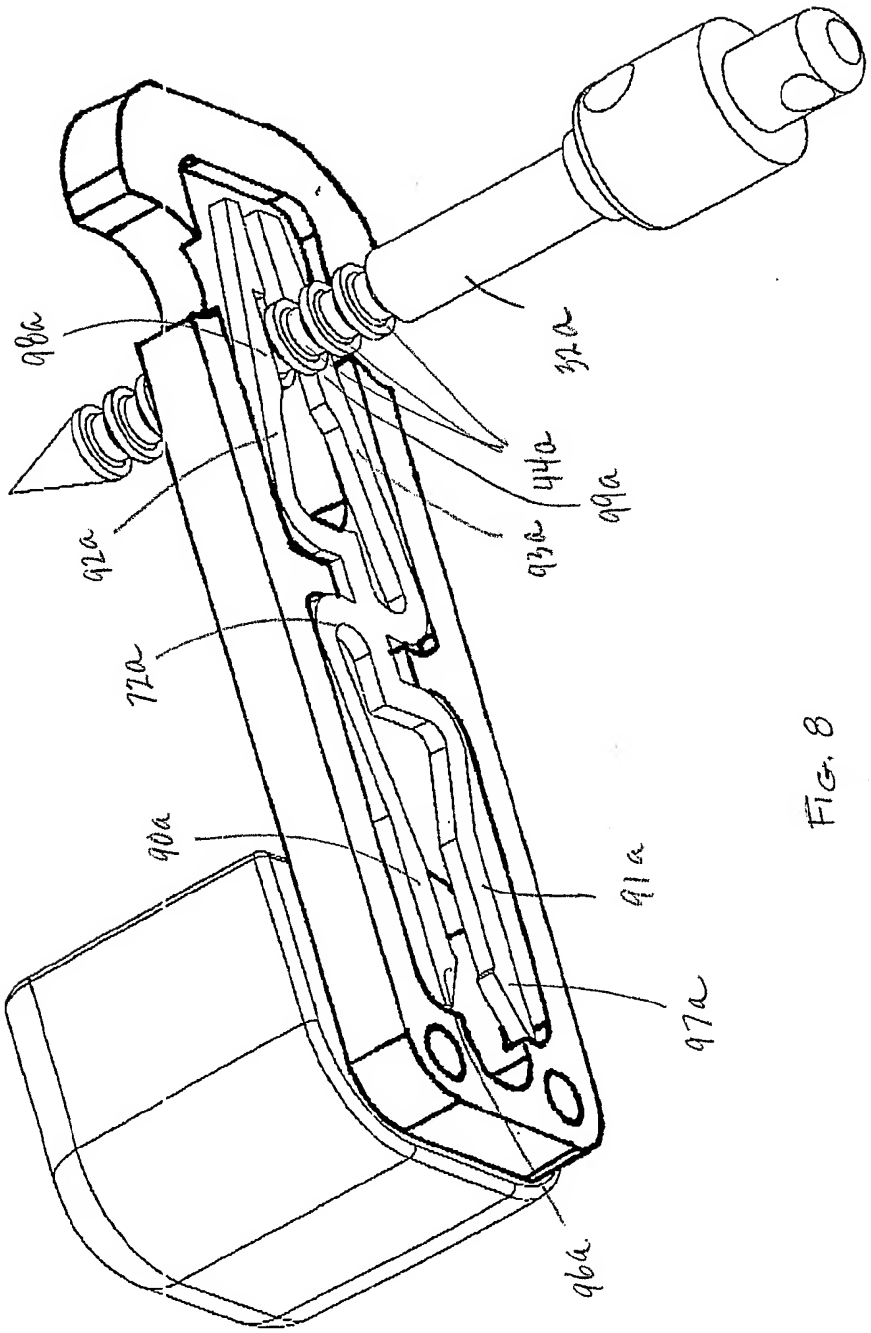

Fig. 8

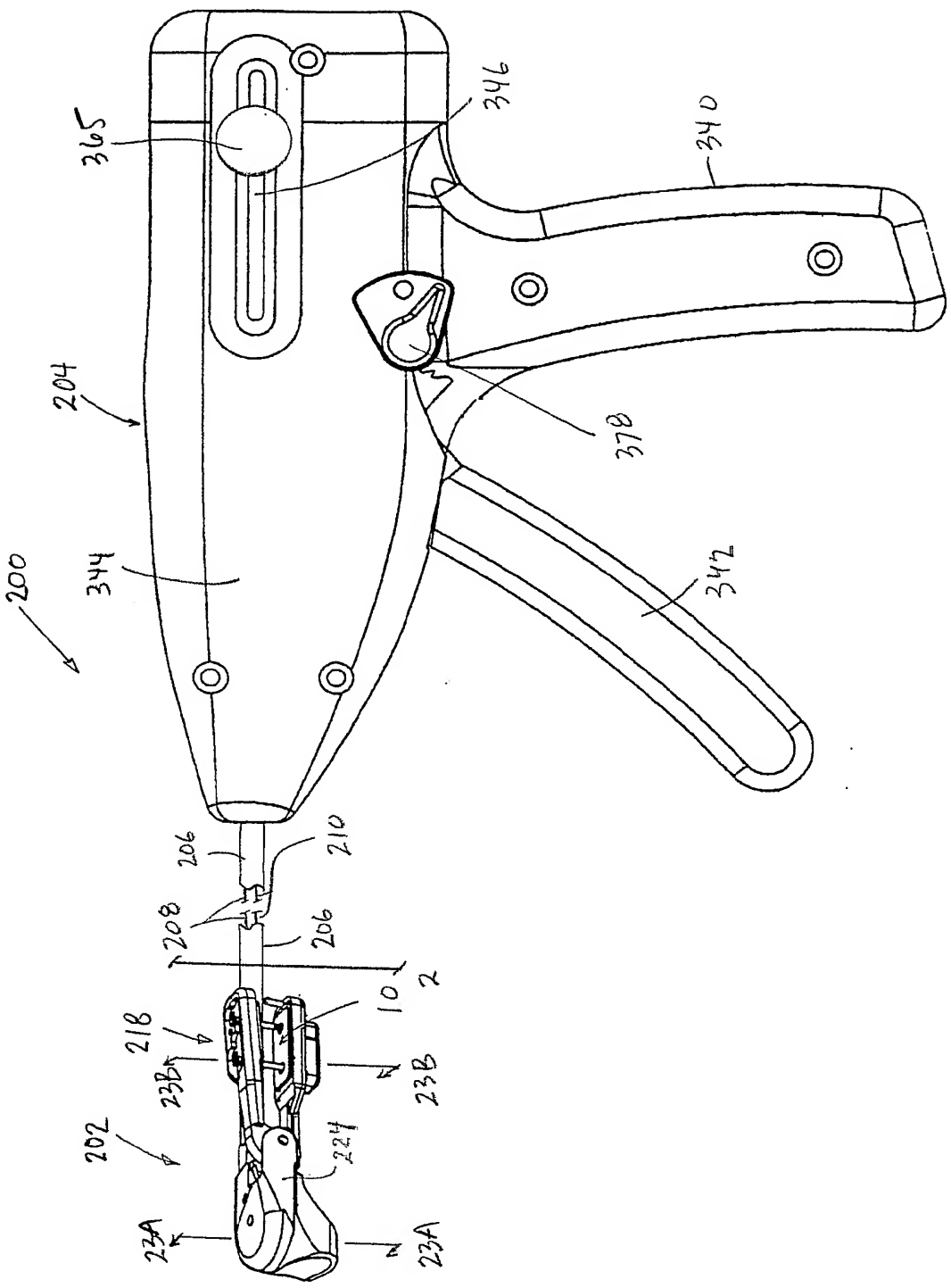
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FIG. 9

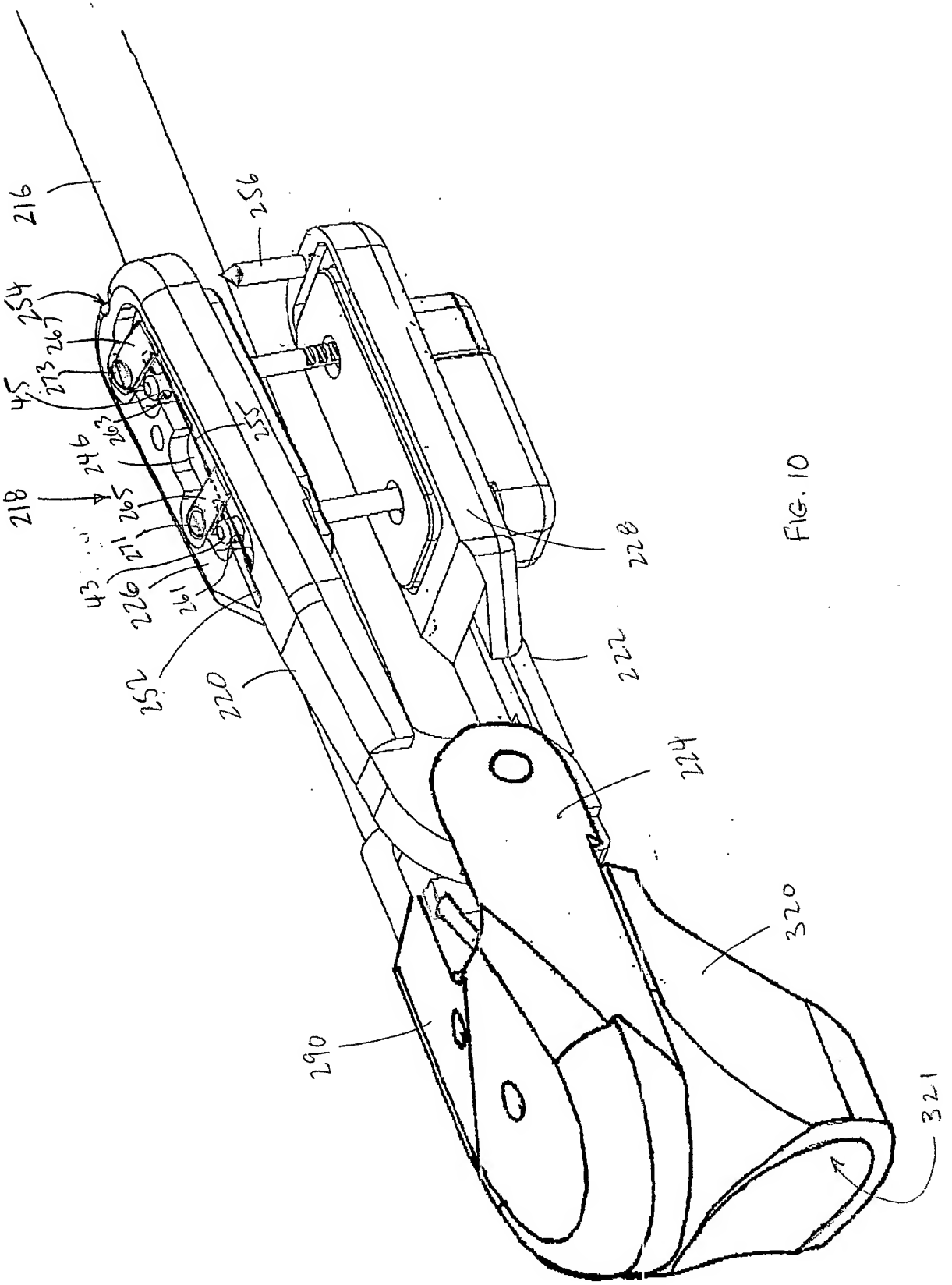
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FIG. 10

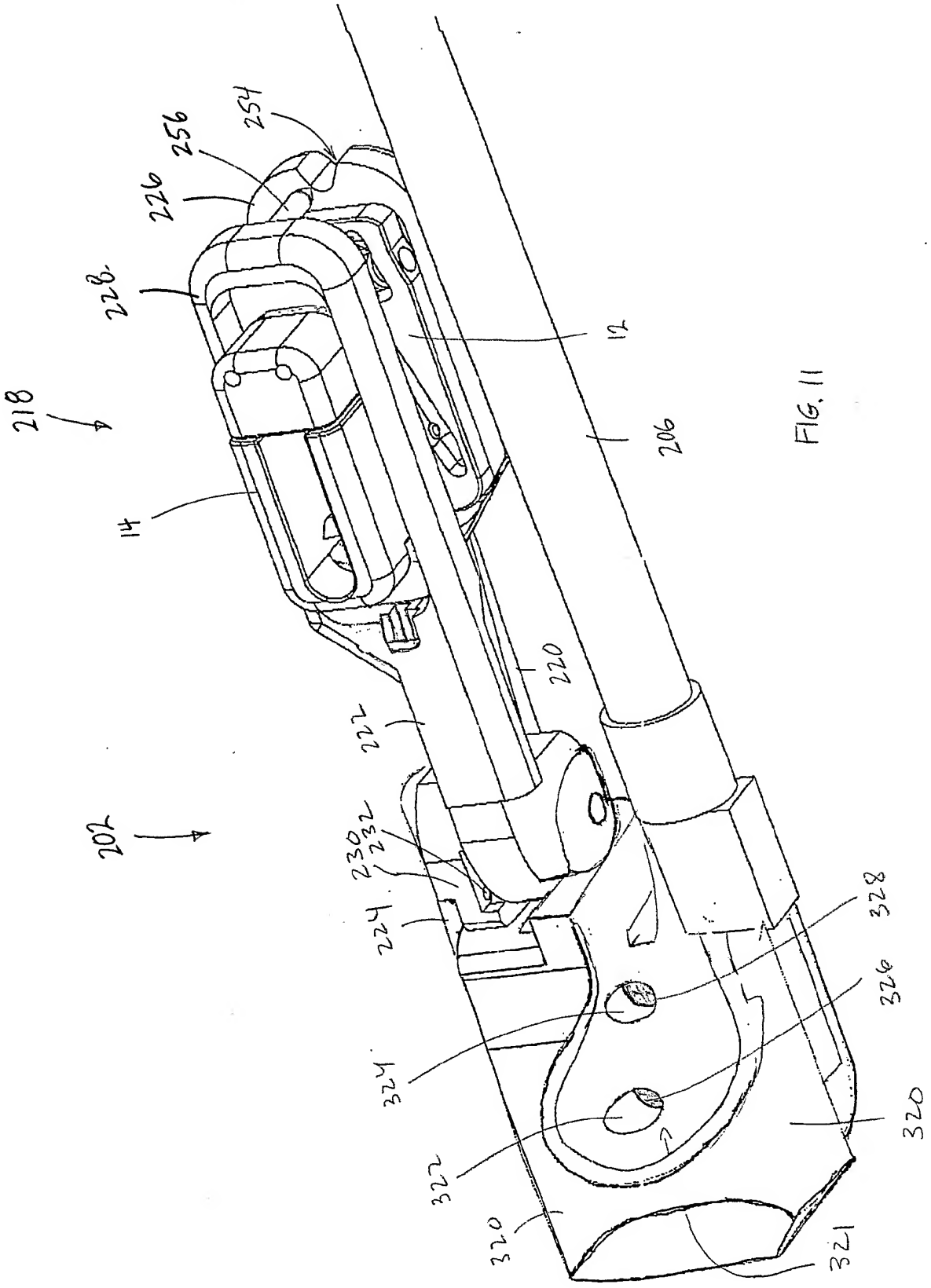
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FIG. 11

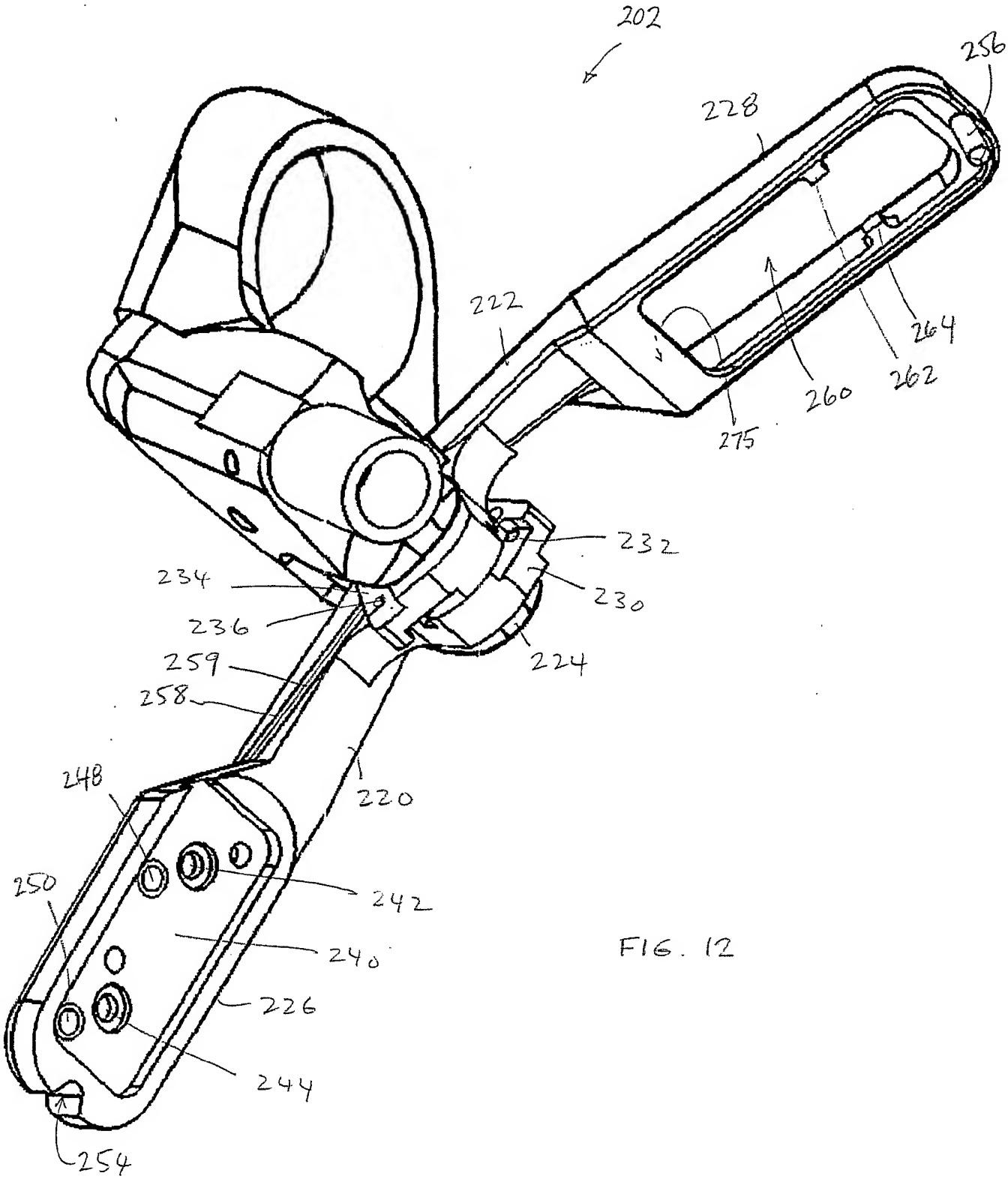
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FIG. 12

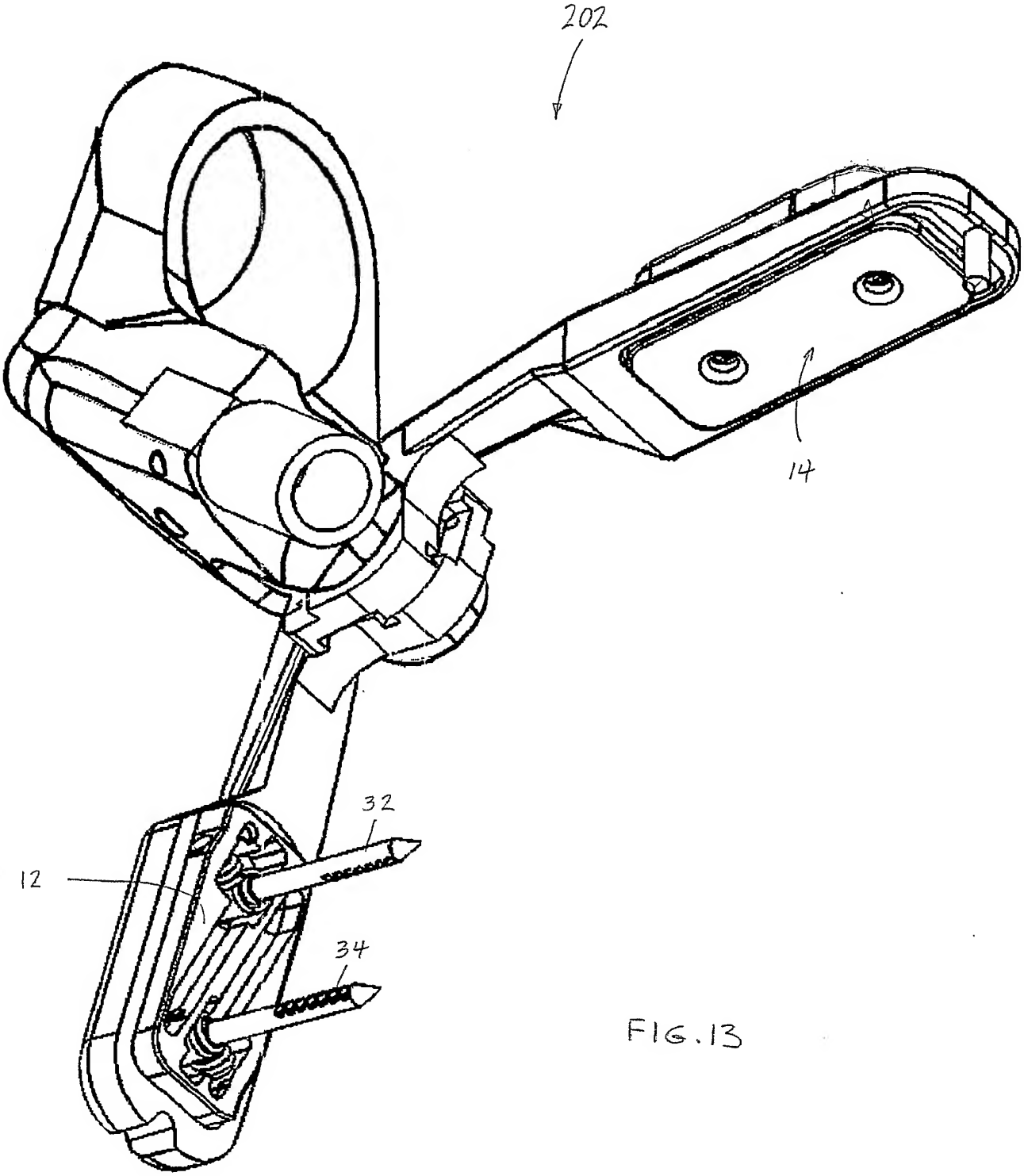


FIG. 13

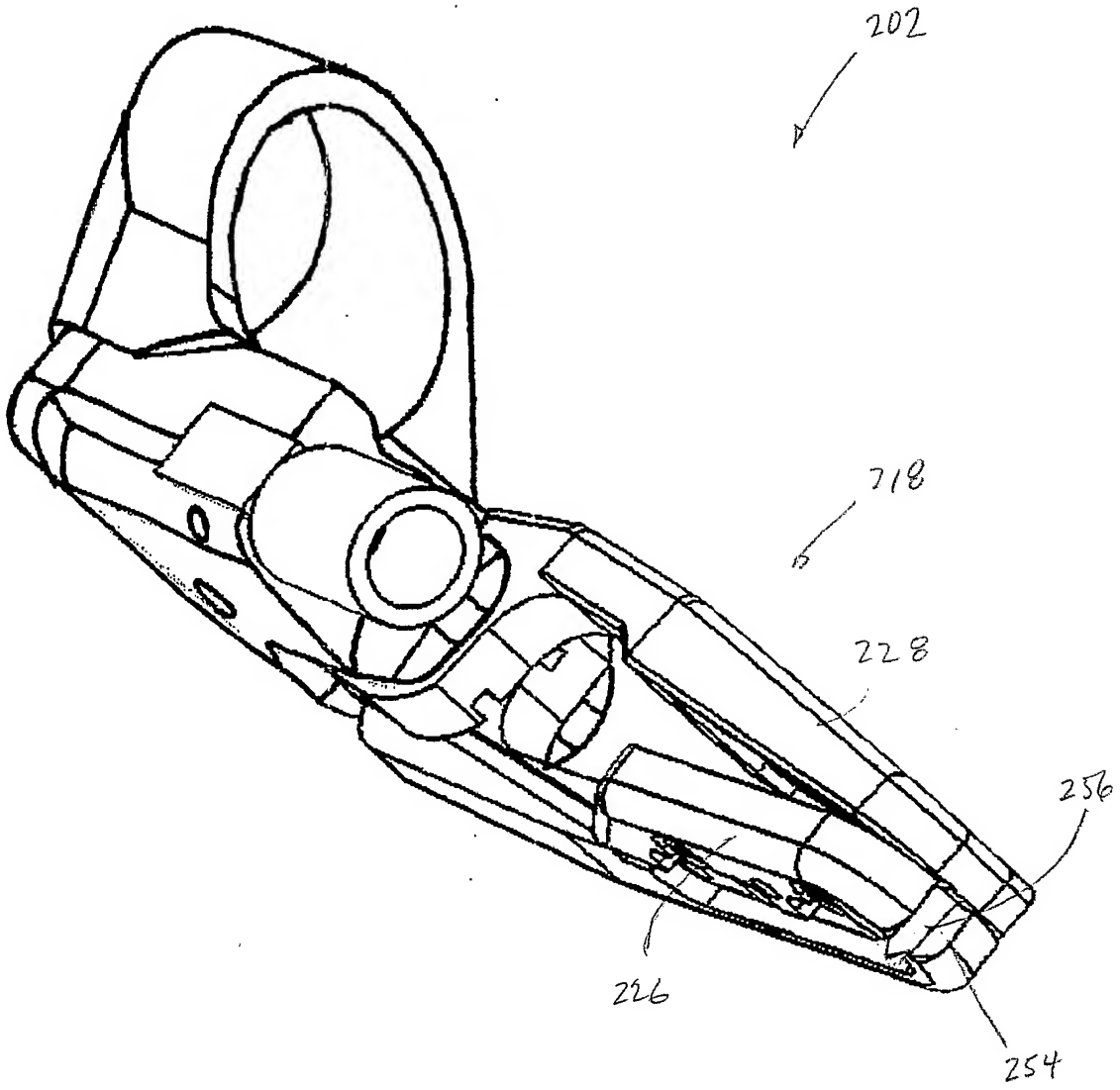
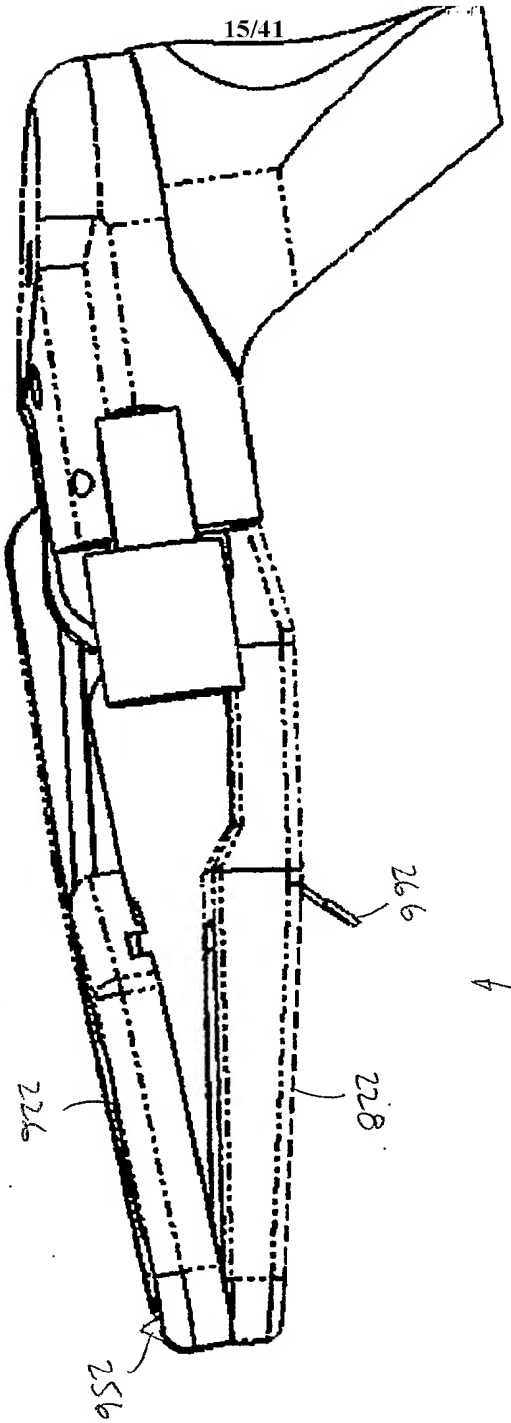


FIG. 14



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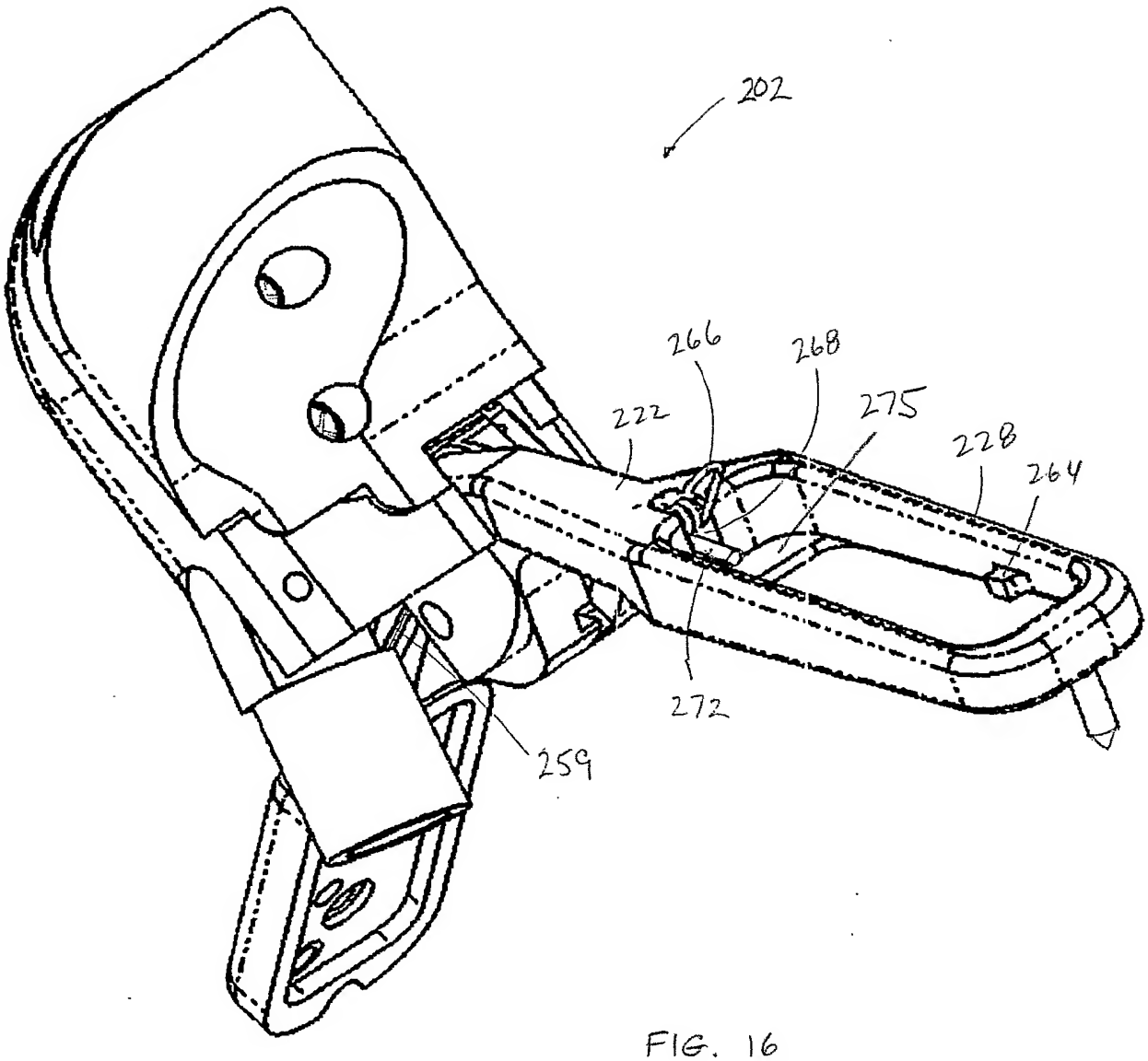
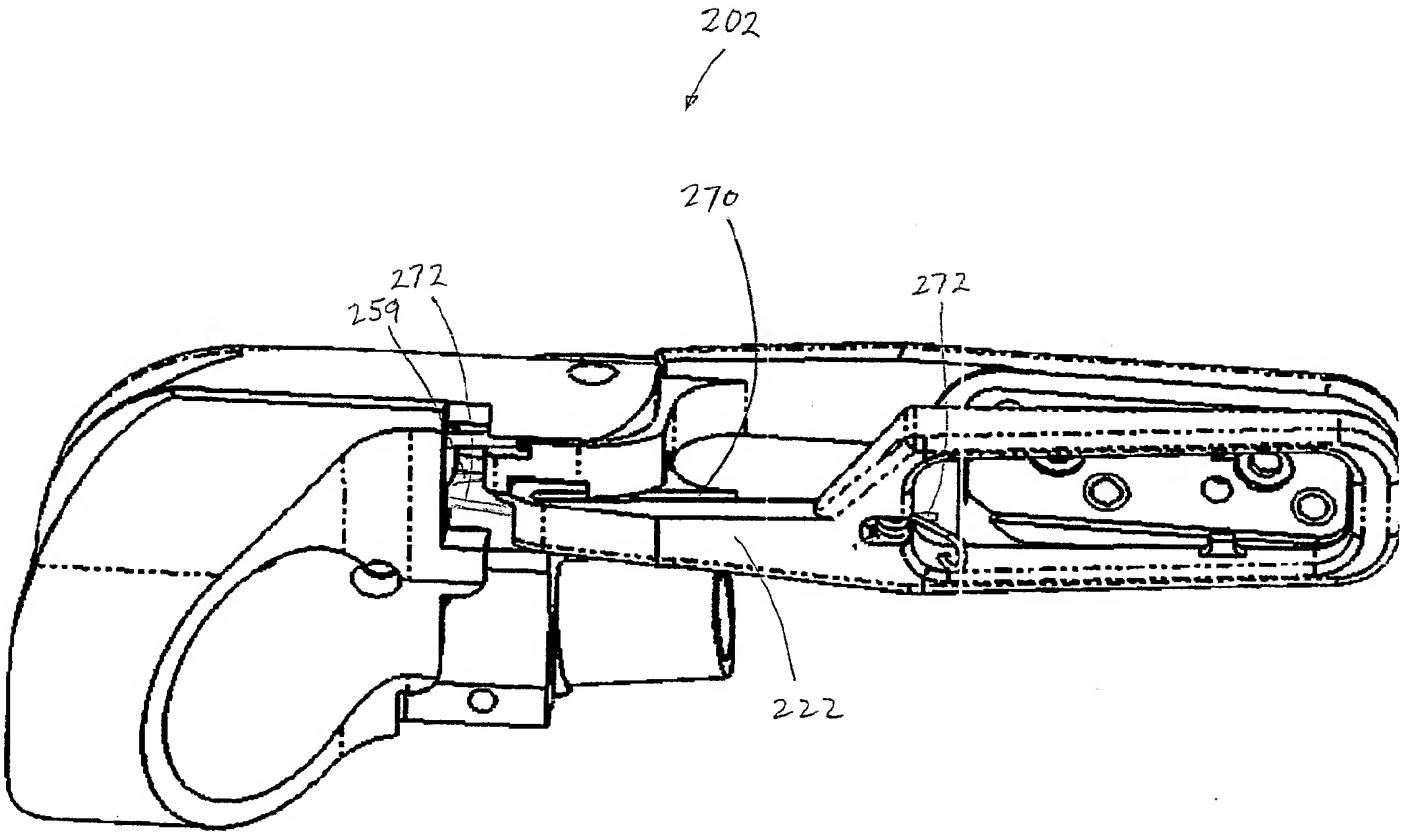


FIG. 16



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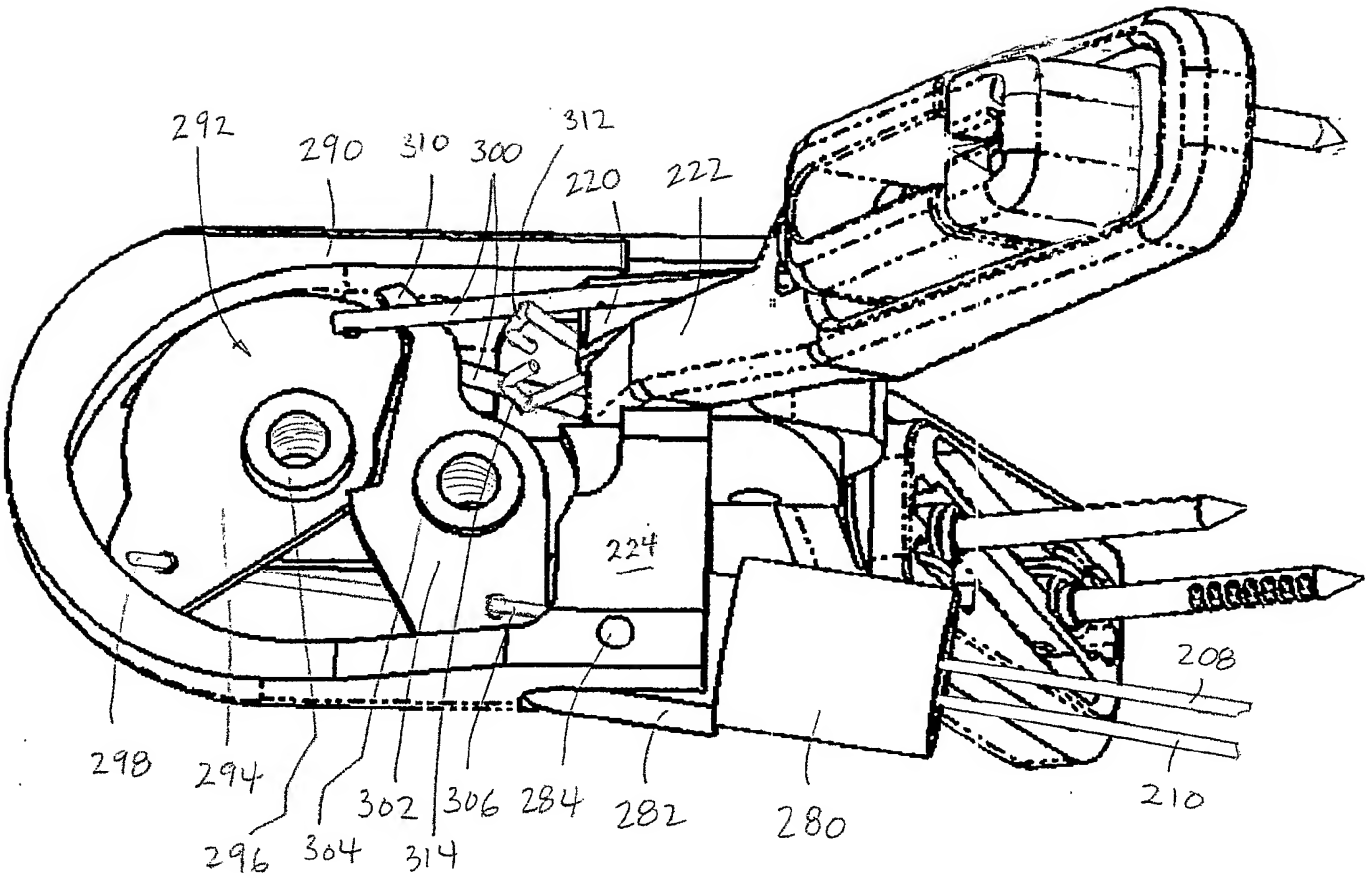
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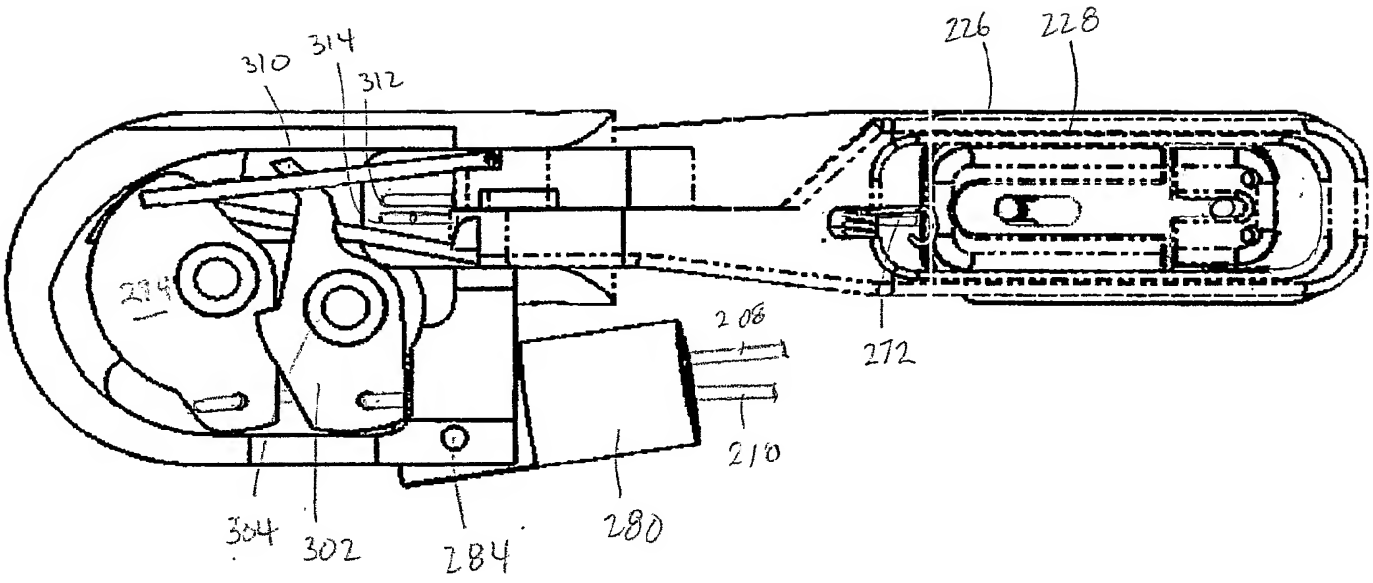
FIG. 18



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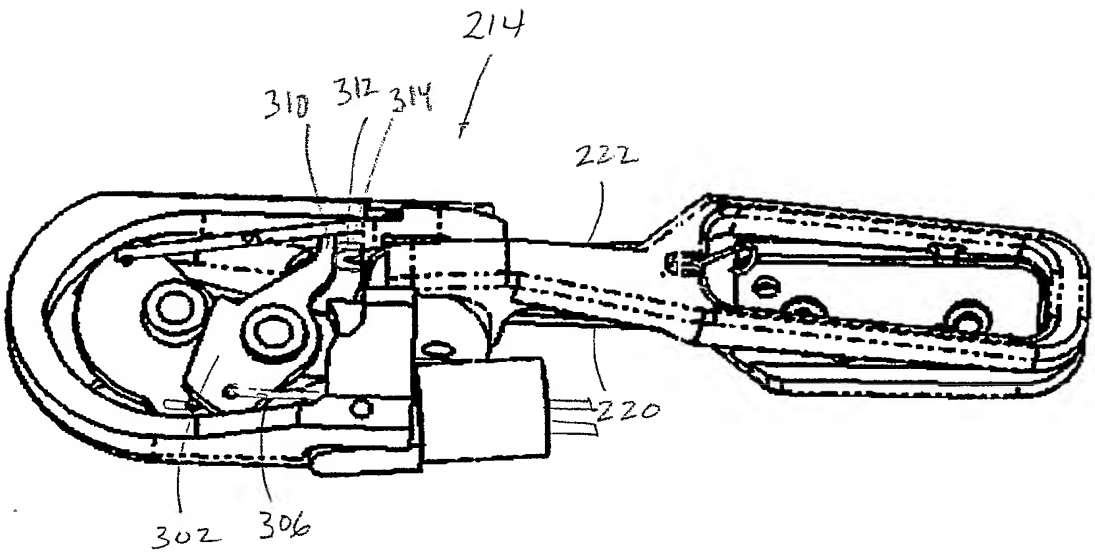

FIG. 20

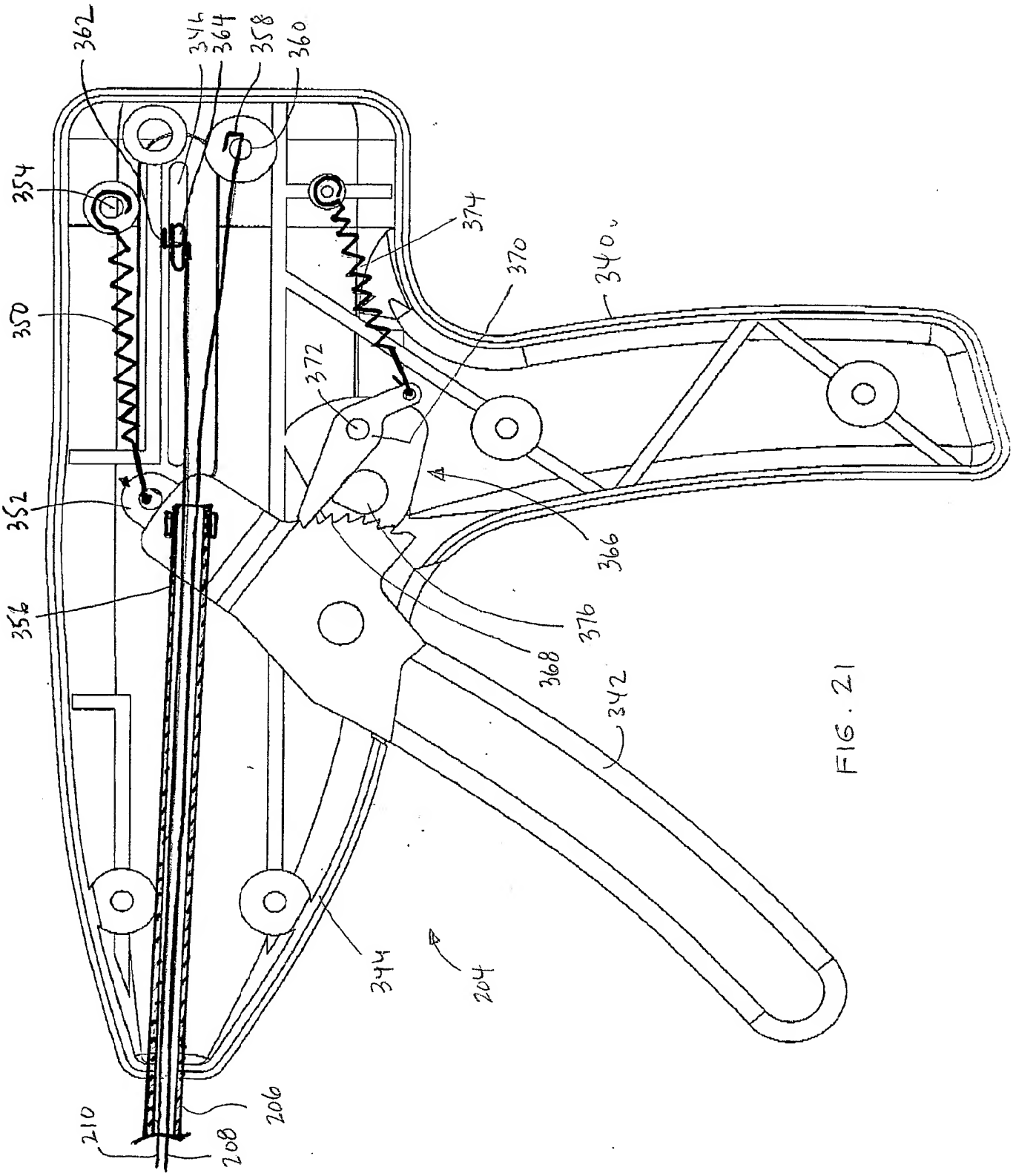
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FIG. 21

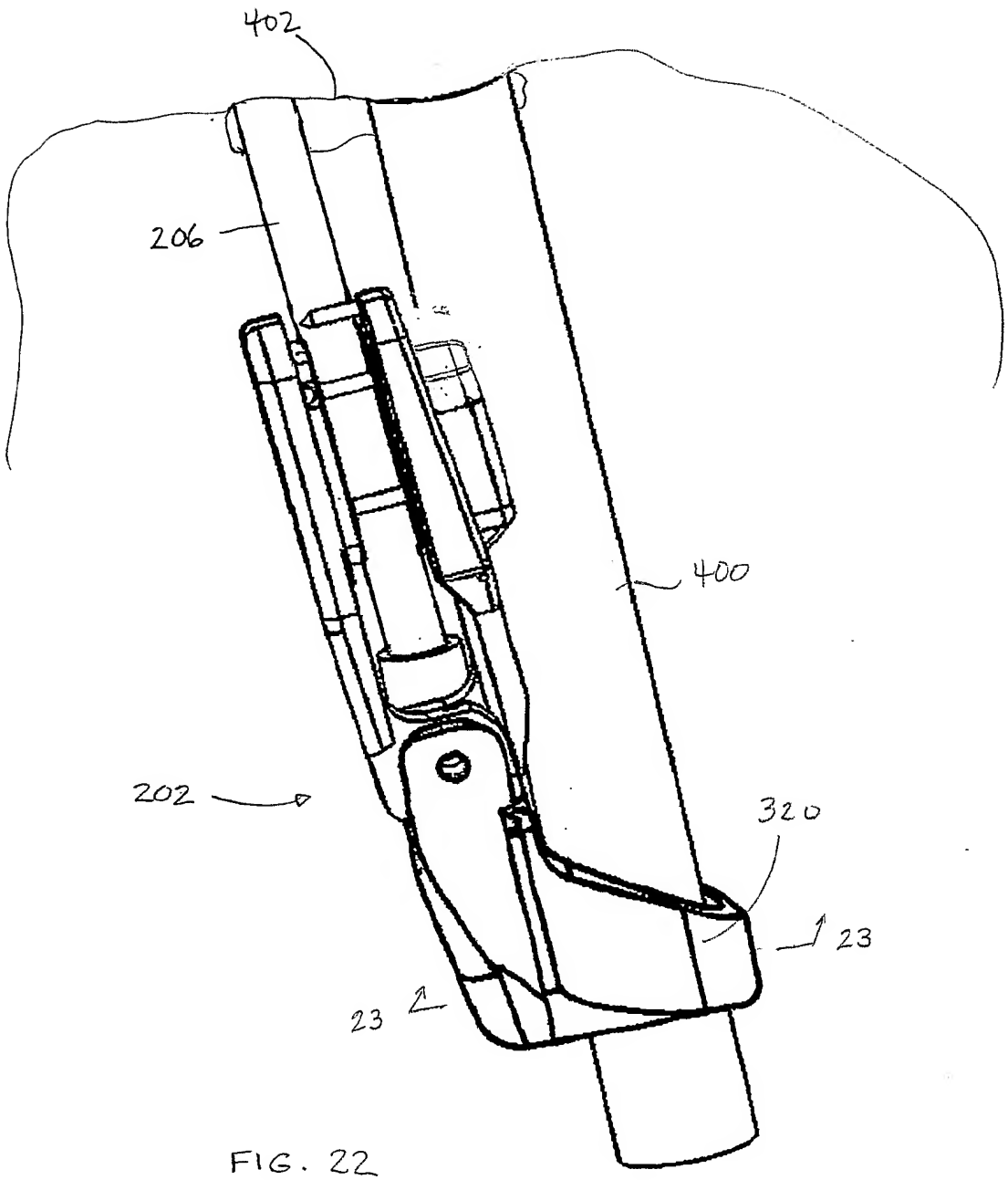

FIG. 22

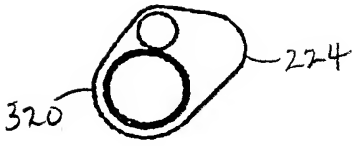

FIG. 23A

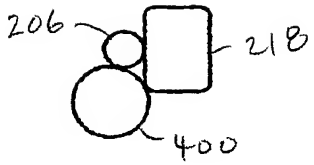

FIG. 23B

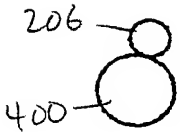

FIG. 24

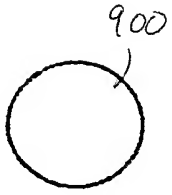

FIG. 25
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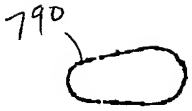

FIG. 46

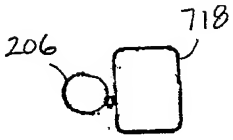

FIG. 47

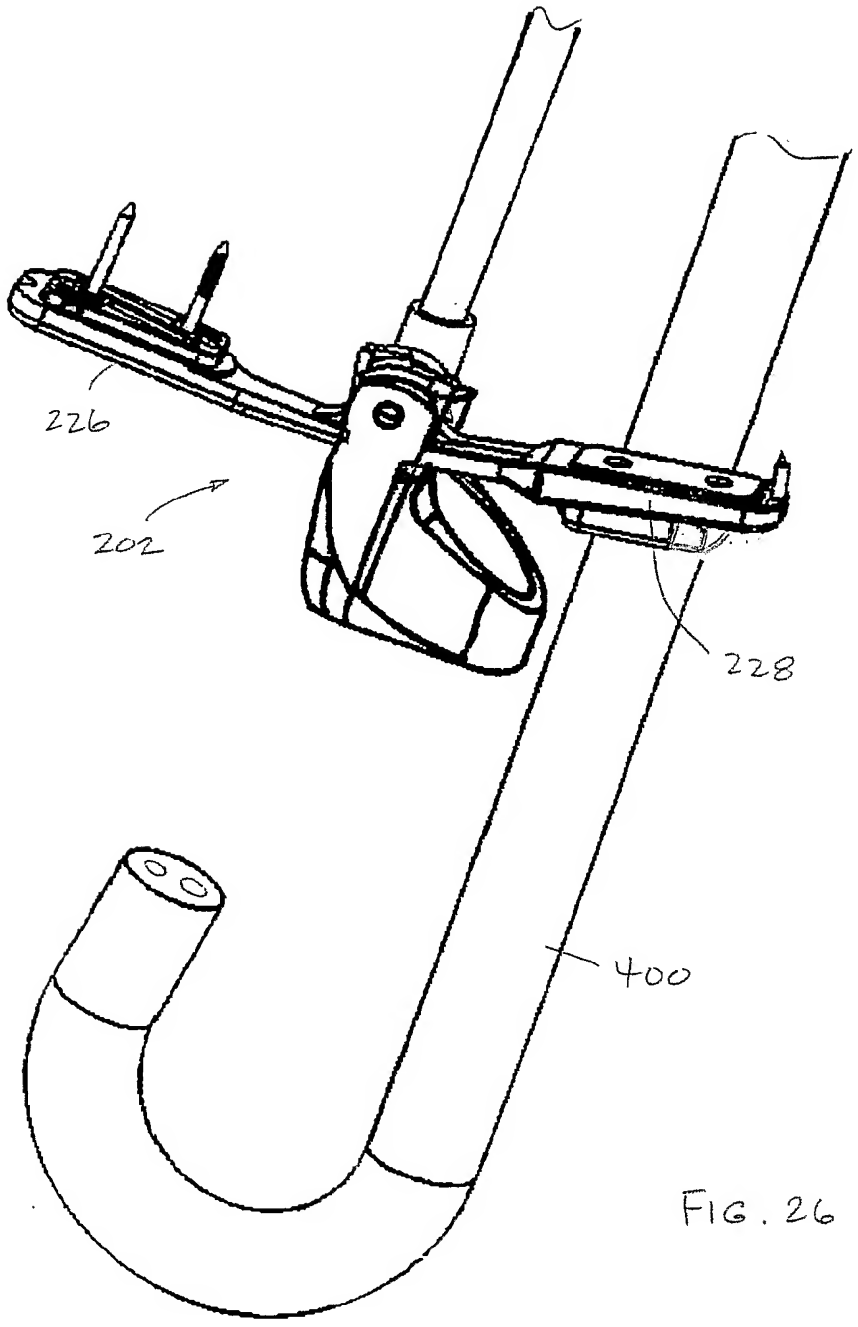

FIG. 26

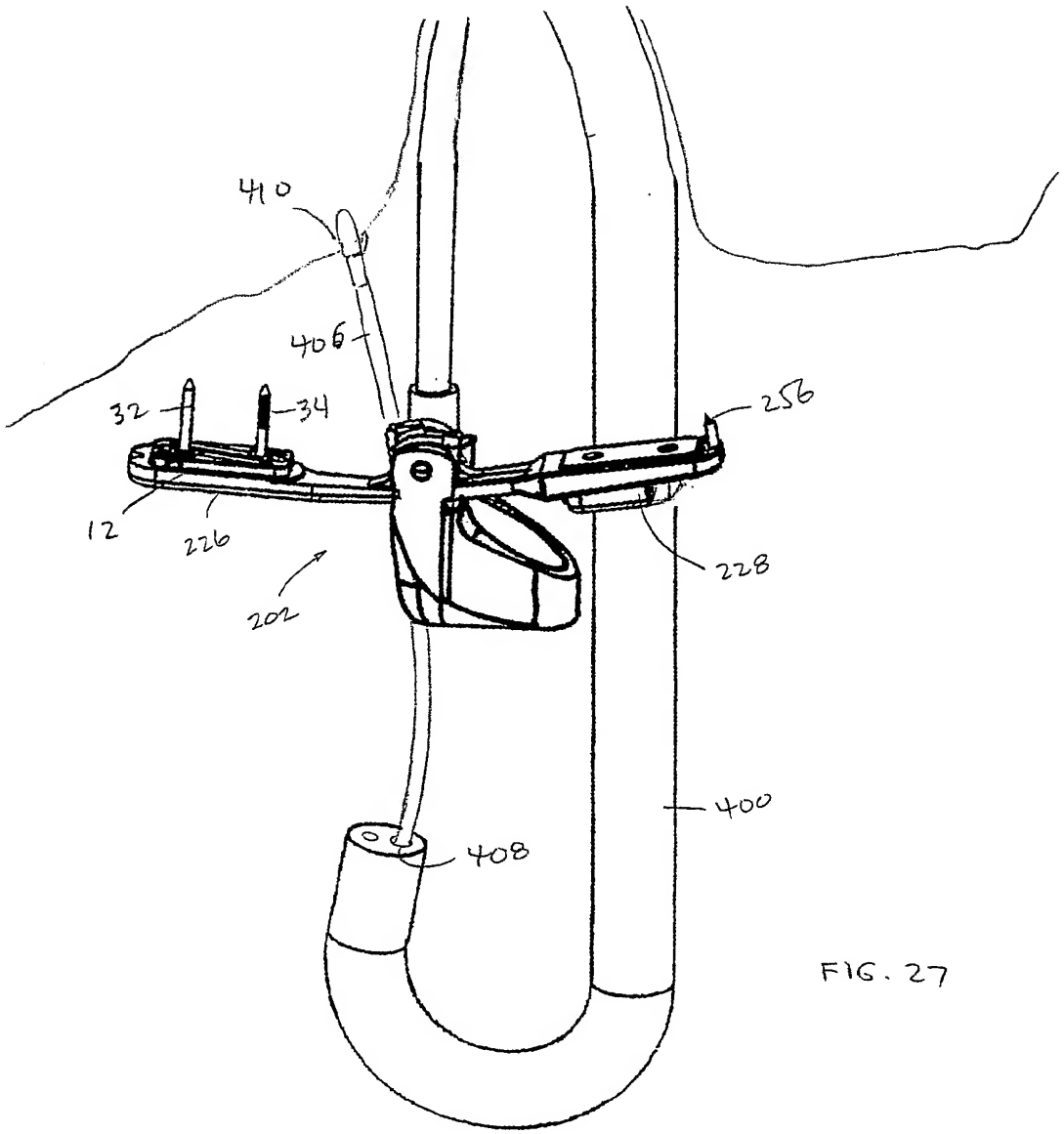

FIG. 27

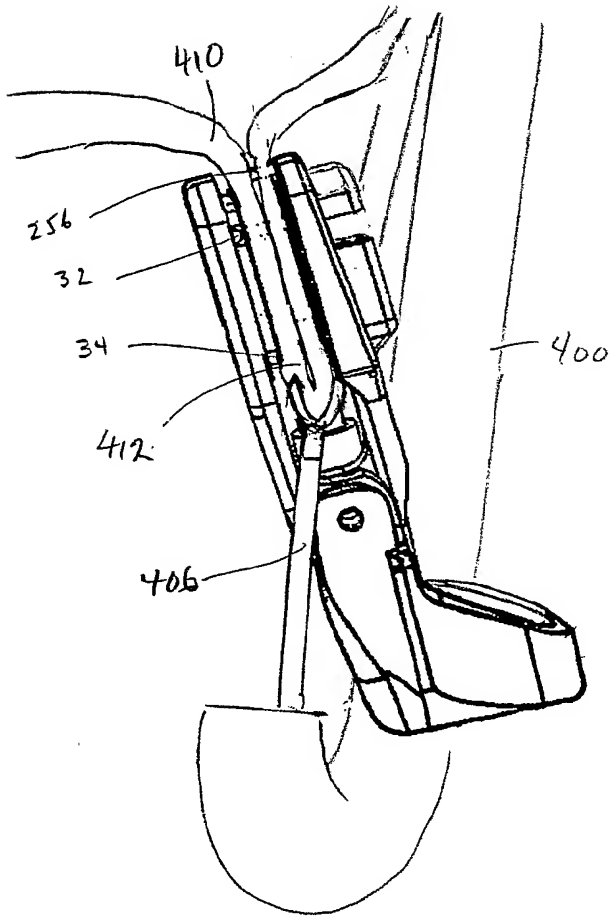

FIG. 28

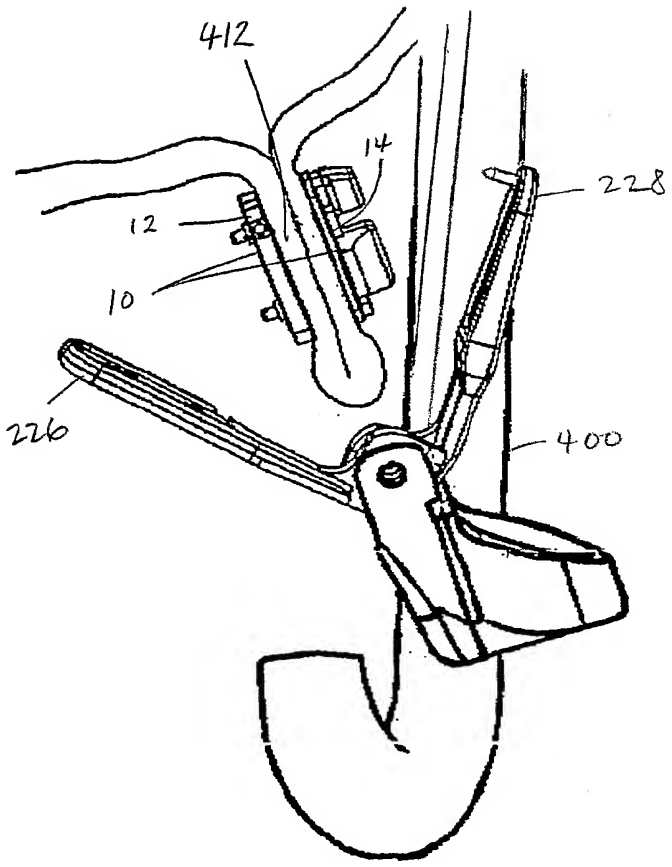

FIG. 29

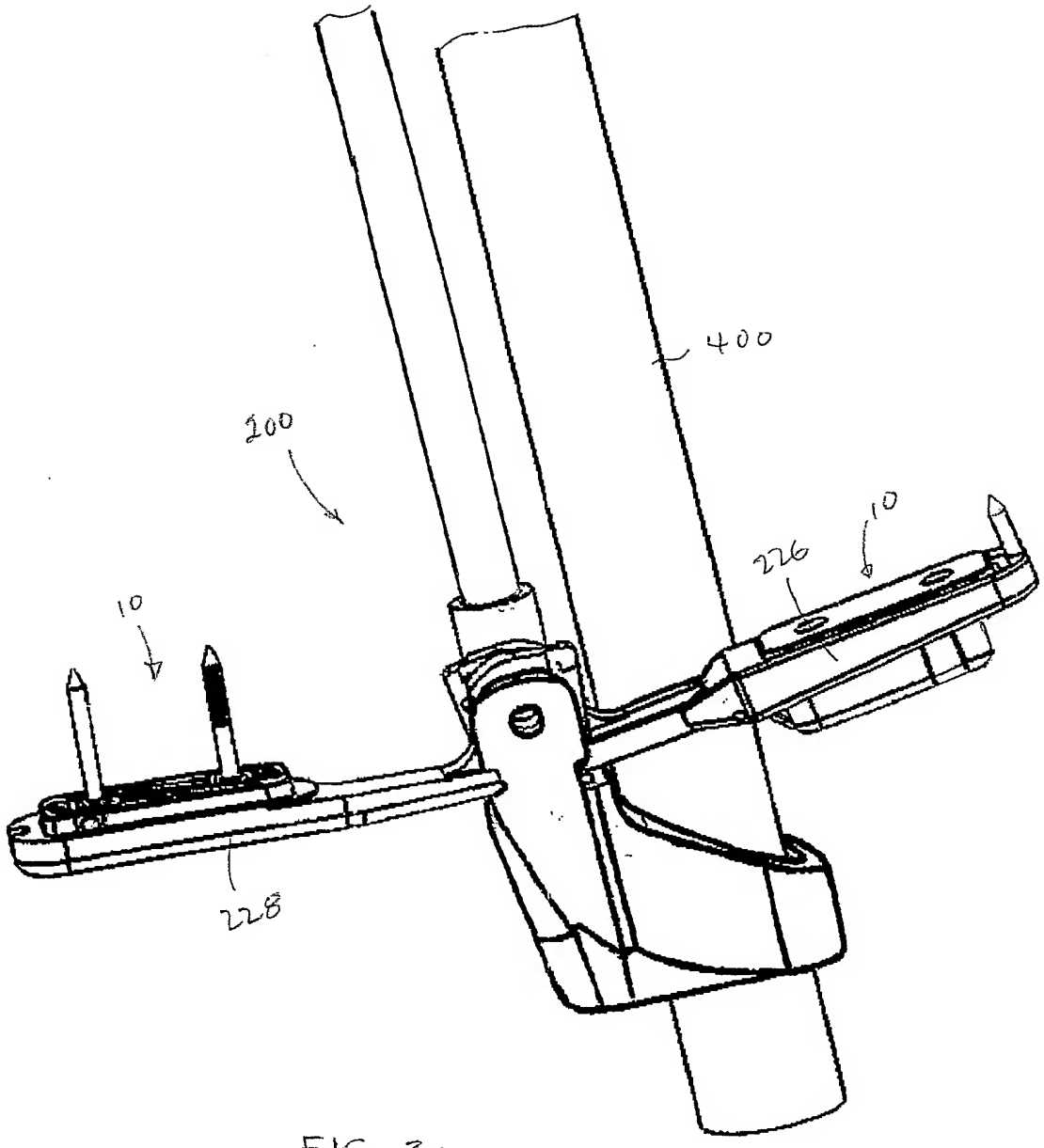

FIG. 30

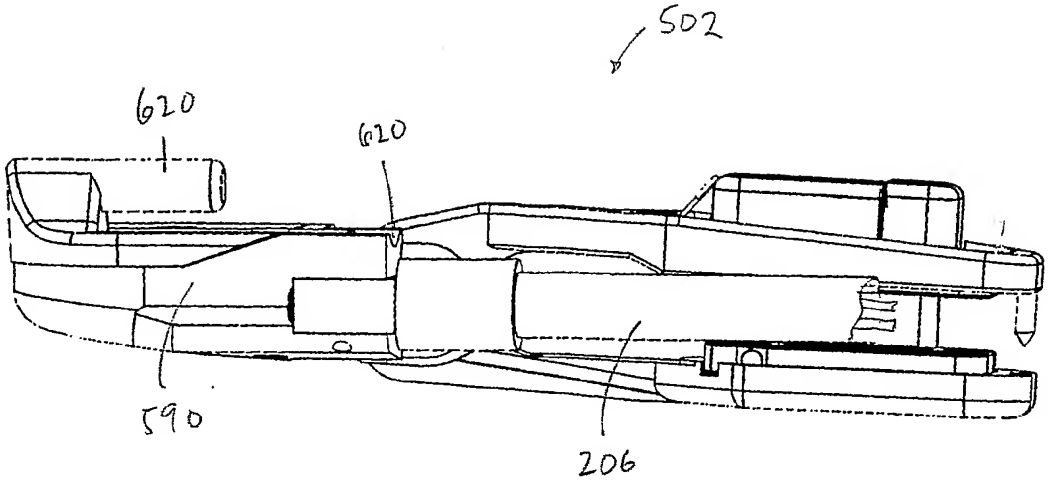

FIG. 31

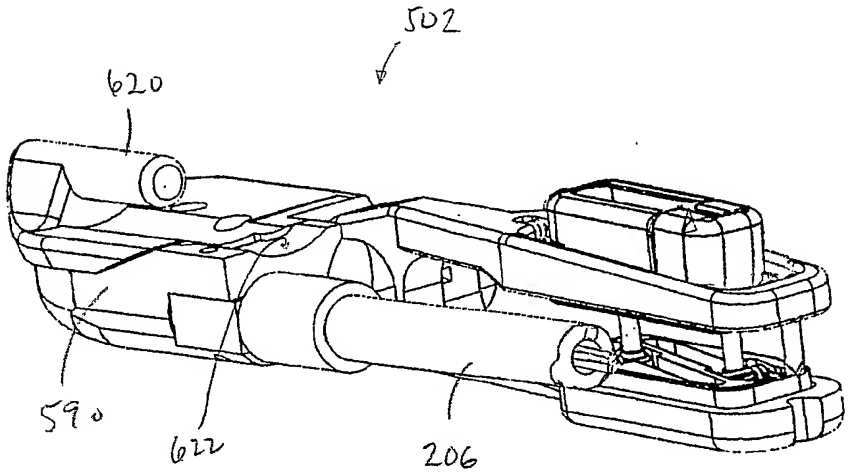

FIG. 32

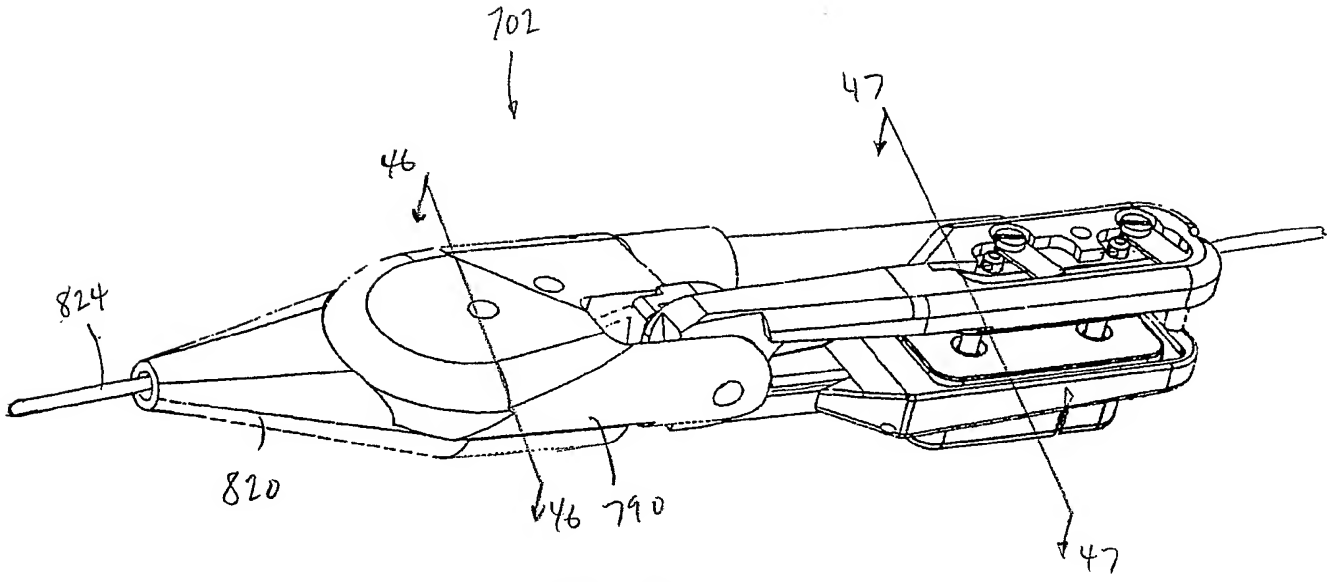

FIG. 33

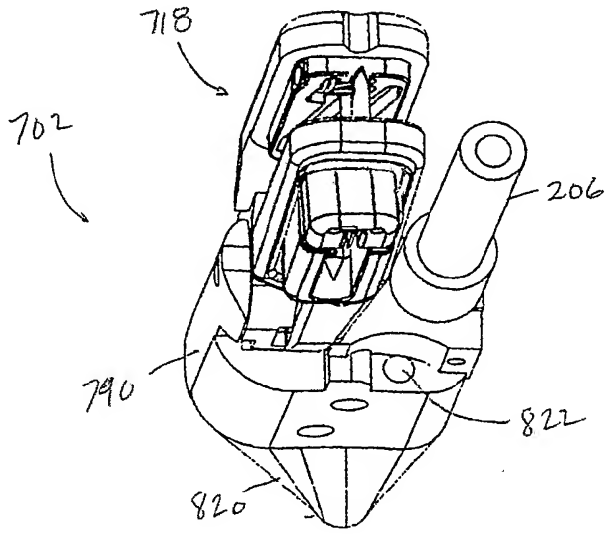

FIG. 34

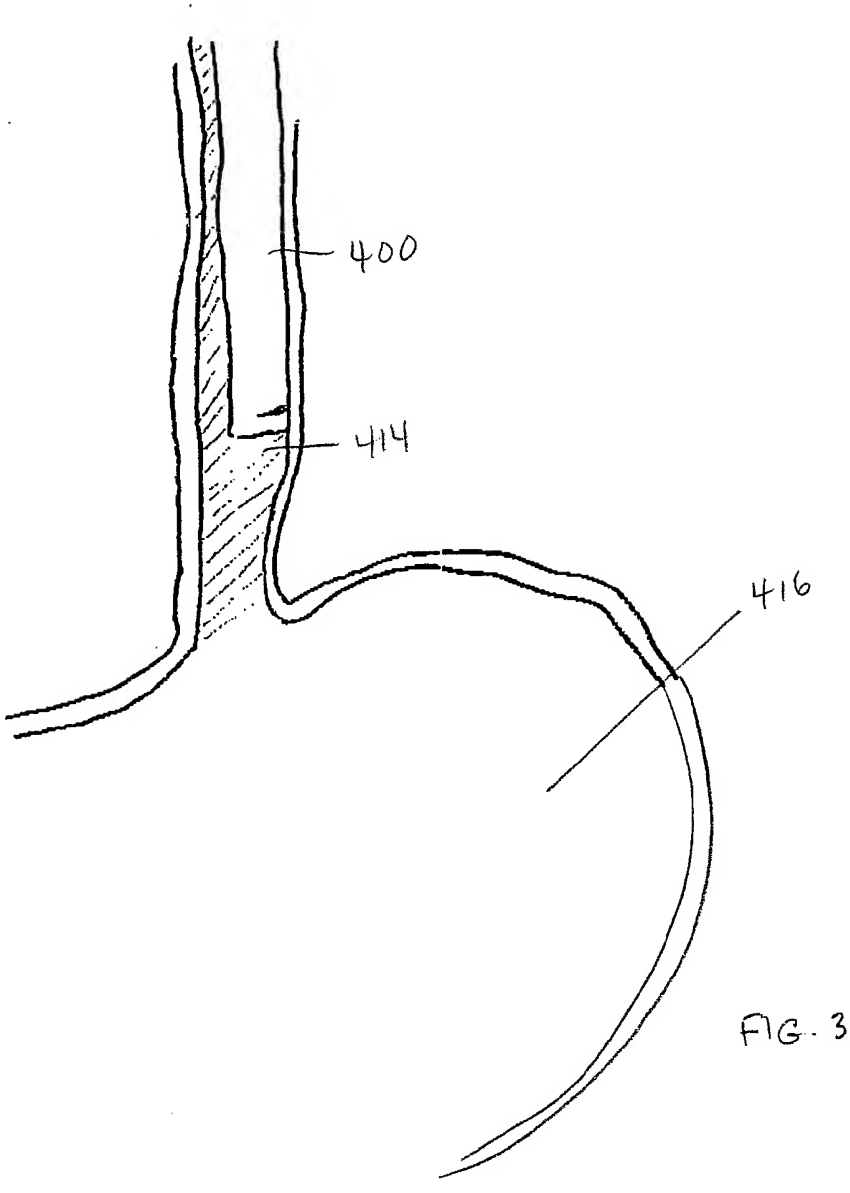

FIG. 35

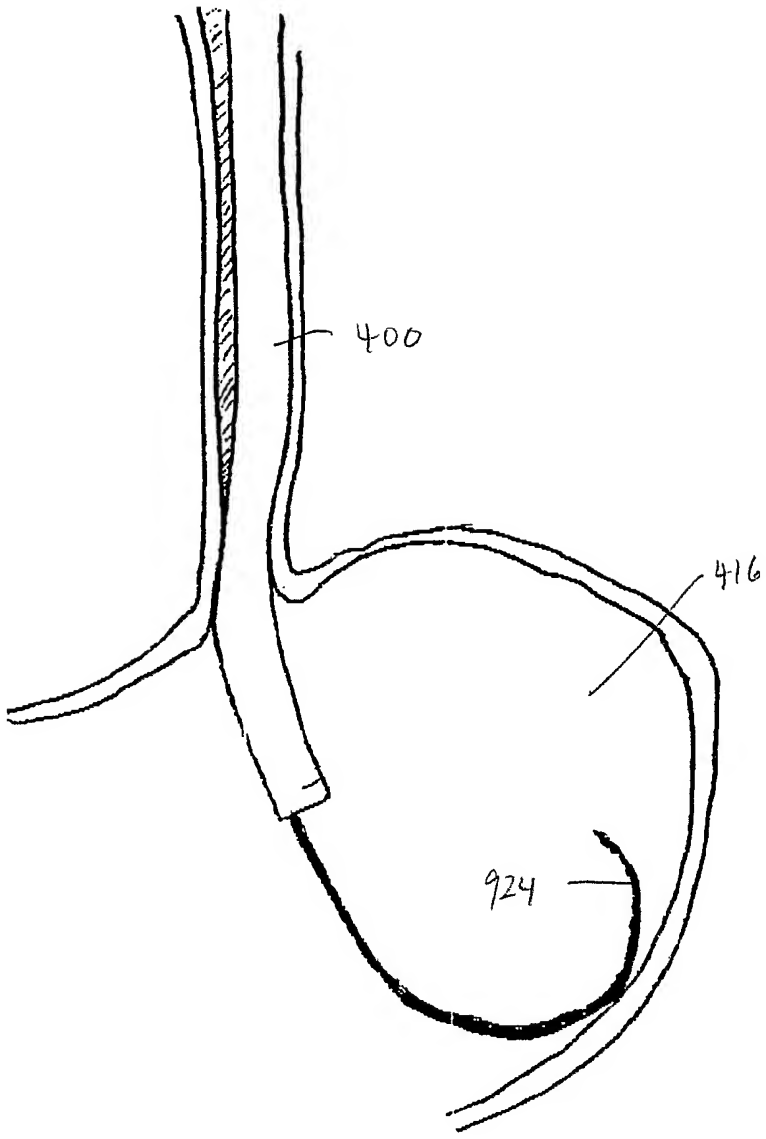

FIG. 36

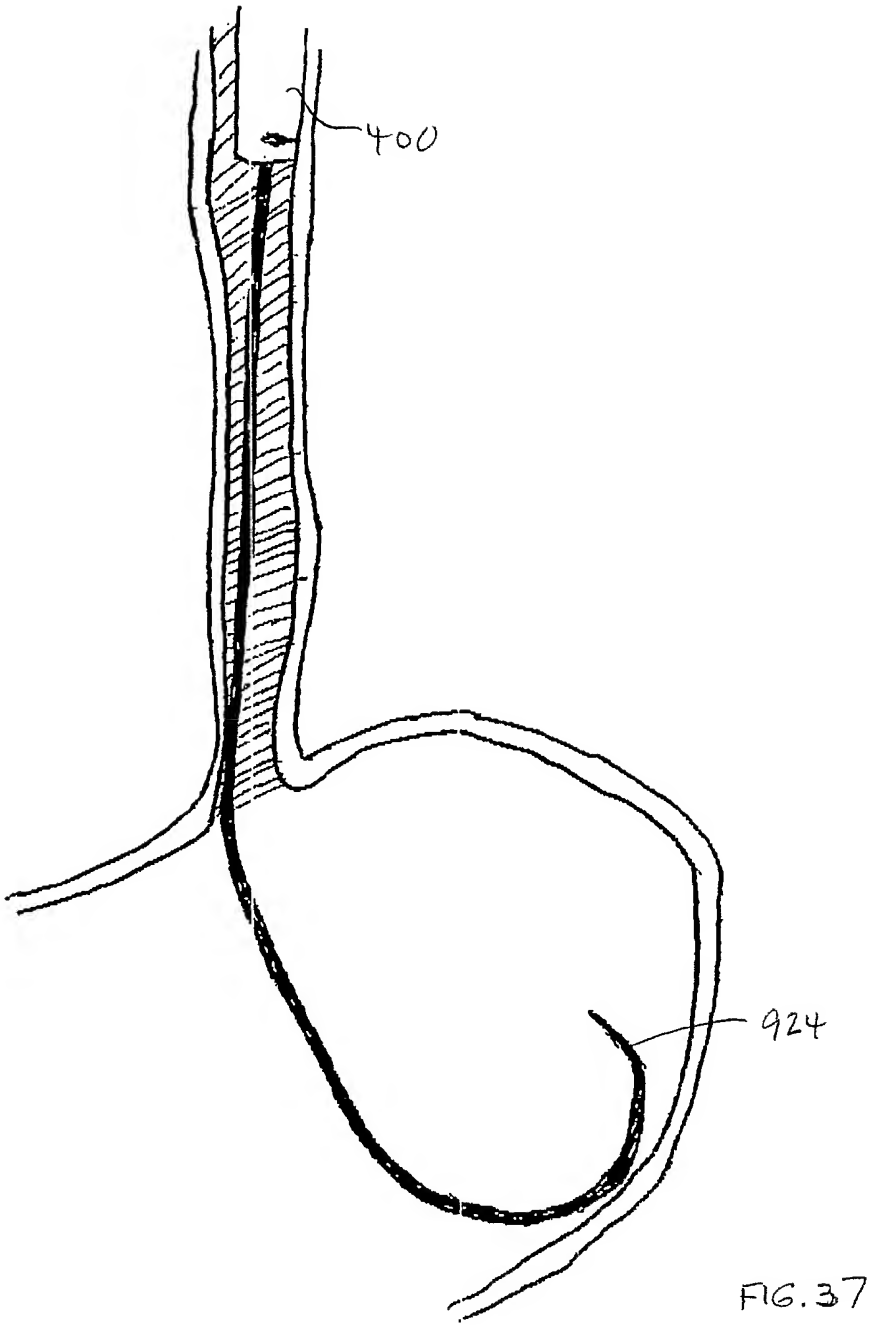

FIG. 37

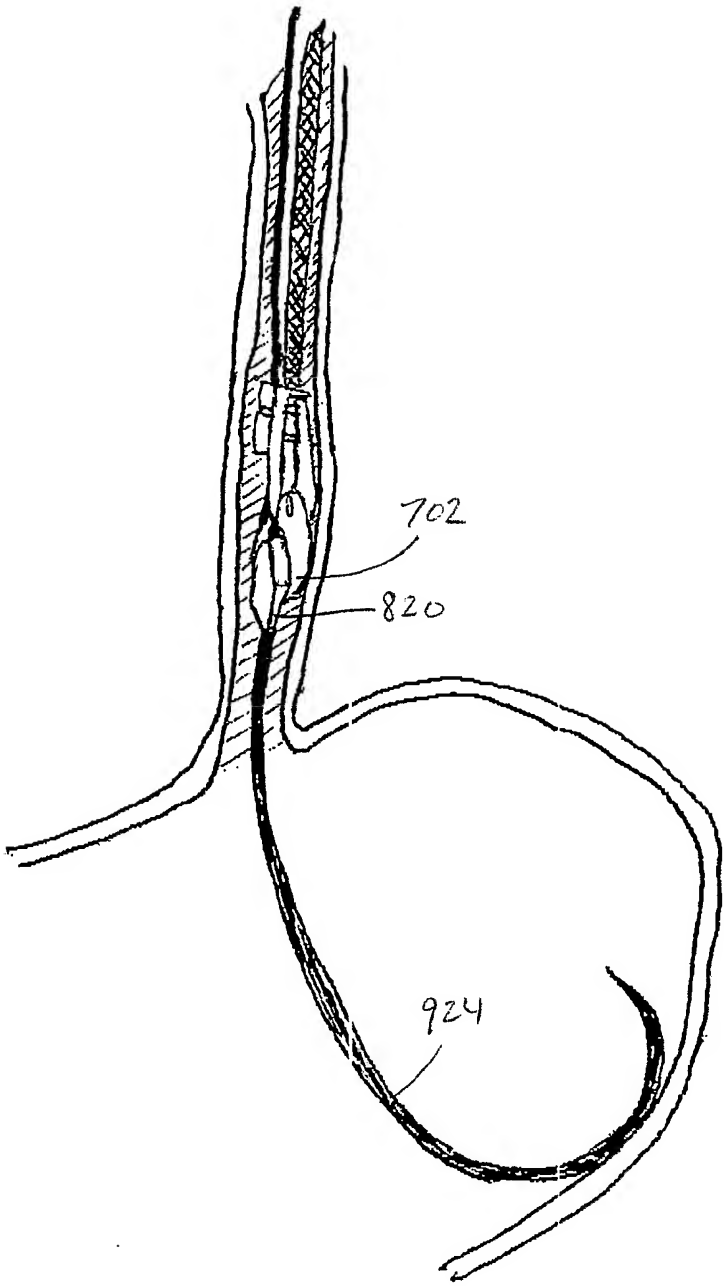

FIG. 38

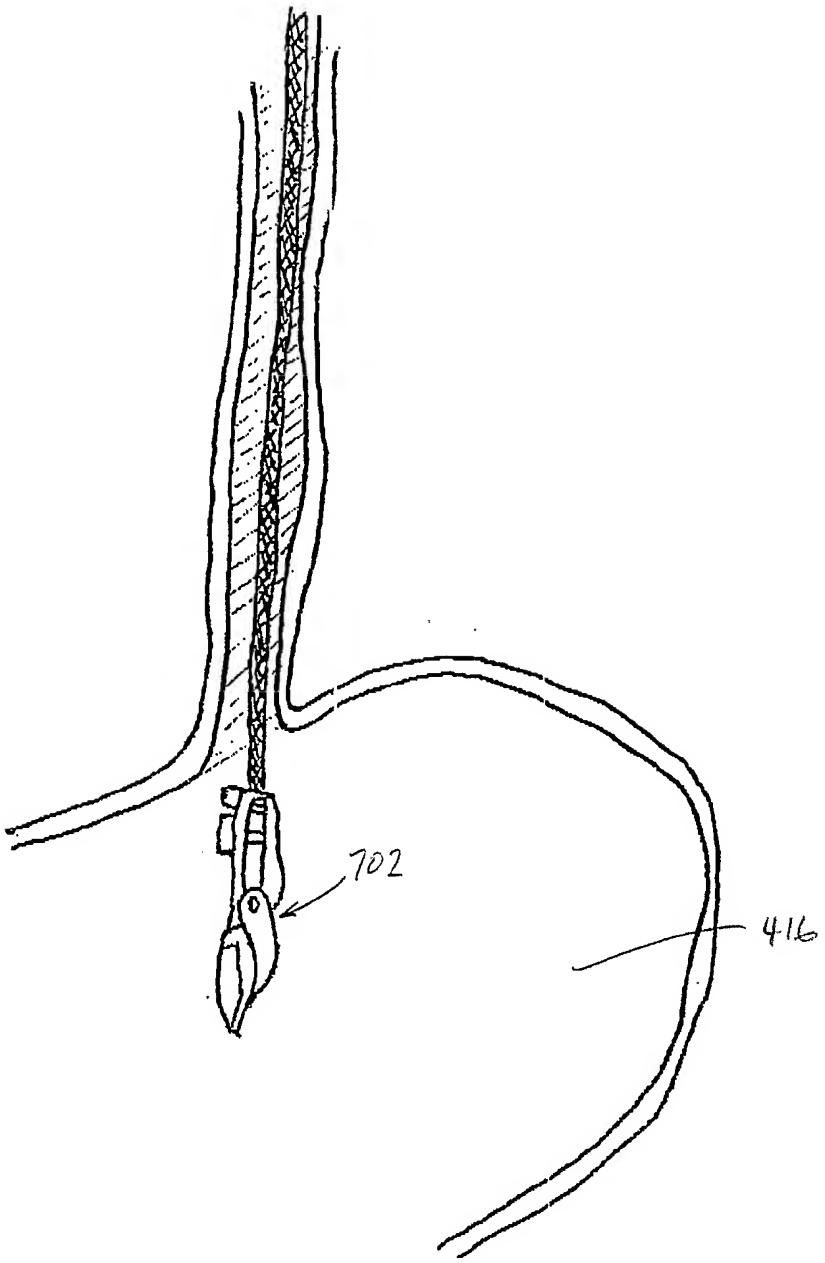

FIG. 39

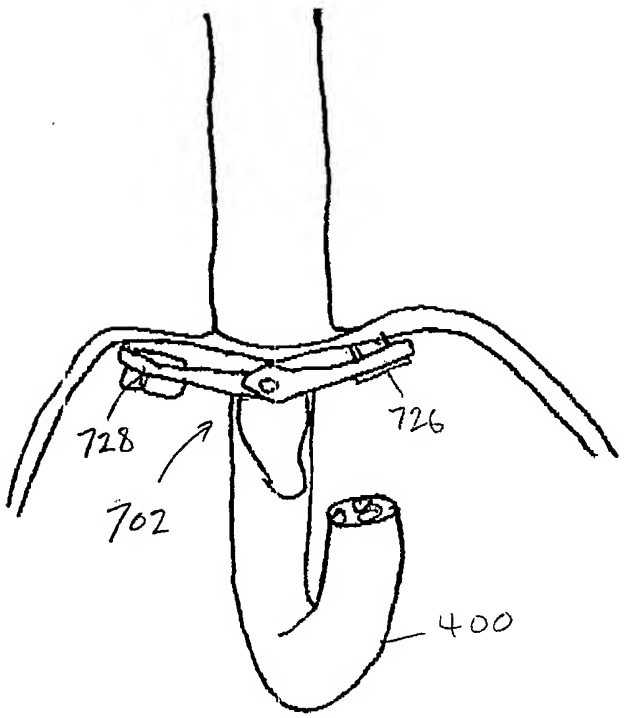

FIG. 40

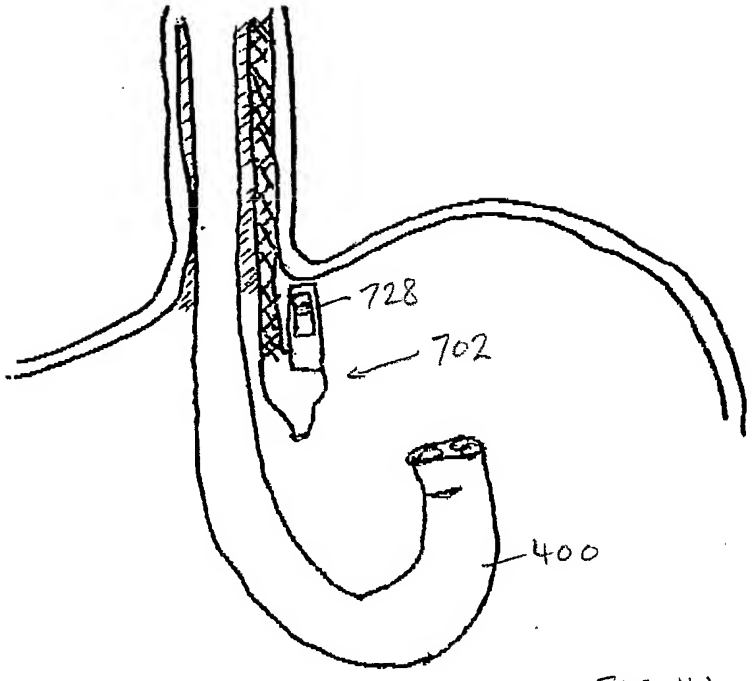

FIG. 41

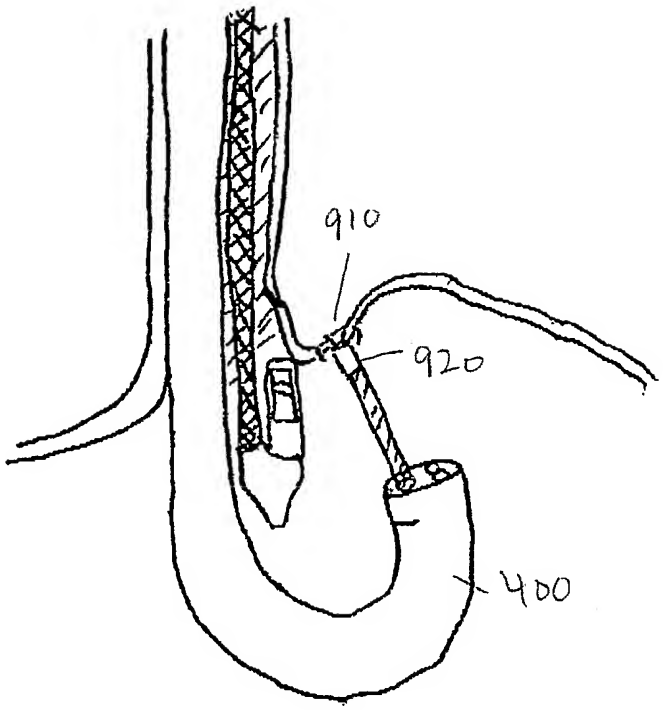

FIG. 42

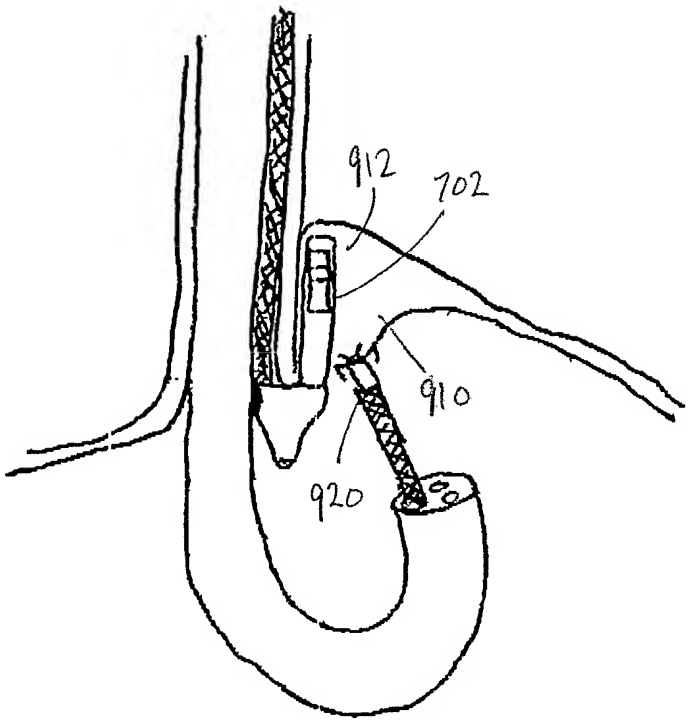

FIG. 43

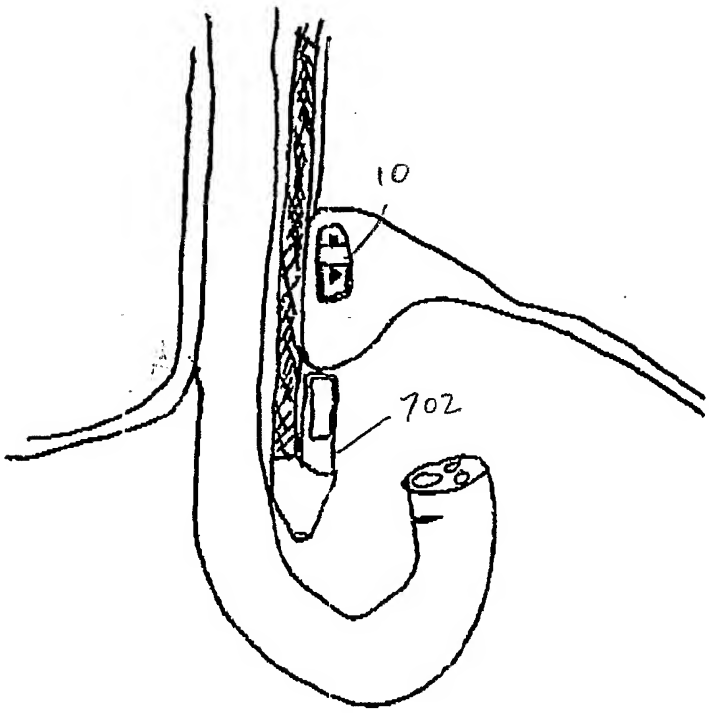

FIG. 44

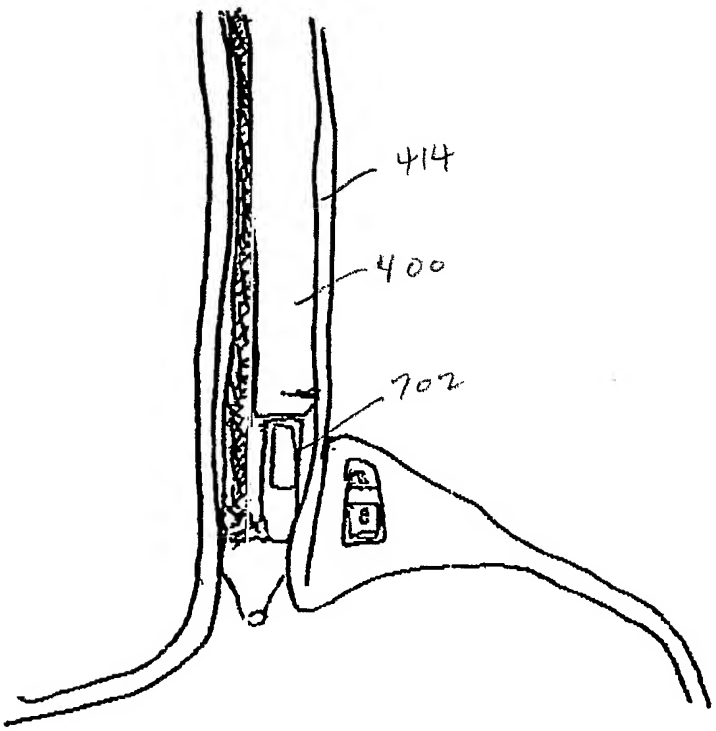

FIG. 45